

SCOPE



The Official Newsletter of the ASQ Orange Empire Section

January 2009

Section Chair Column - ASQ Letter from the Chair



Happy New Year and welcome to 2009! I hope all of you had good and safe holiday. May this New Year bring many opportunities your way to explore every joy of life and may your resolutions for the days ahead stay firm, turning all your dreams into

reality and all your efforts into great achievements. Time indeed flies and the year 2008 went by so quickly.

The world economy is on the brink of a rare global recession, the World Bank said in a forecast released Tuesday, December 9, 2008, with world trade projected to fall next year for the first time since 1982 and capital flows to developing countries predicted to plunge 50 percent. Based on November 2008 data provided by United States Department of Labor, the unemployment rate was 6.7% which showed continued increase in November. In December 1982, US unemployment rate was 10.8% and some economists forecasted that 2009 unemployment rate to top 10.8%. Based on my conversation during our section's monthly dinner meeting, some of our members are unemployed and few members were in fear of losing jobs in 2009. I would encourage all members to think about updating their skills by earning ASQ certifications. Not only it will help you to find a job, it will help you to enhance your knowledge. As quoted by Bel Kaufman, the educator and editor, "Education is not a product, mark, diploma, job, money, in that order; it is a process, a never ending one."

During this difficult time, we will be happy to help you out. I encourage you to start thinking about your next career. We can hold a clinic to update your resume. We can start weekend training classes that can help you to refresh your skills. If you're changing career paths totally, it's a good time to enter a training program or register for classes to prepare you. You can contact volunteer organizations that teach needed skills for employment. My family members volunteer at South County Outreach (SCO) – a nonprofit organization that provides comprehensive services to seniors and families. SCO's computer learning lab provides computer training for individuals who are unemployed or underemployed. You can reach SCO by e-mail (<http://www.sco-oc.org/clc.html>) or

by phone (949) 461-9066. Please contact me by e-mail and let me know how we can help.

We need your feedback and invite you to send any suggestions, comments, or whatever else you'd like to express with regard to the Section and section sponsored activities. As all of you know, we have created a position of "VOC Representative" because our section is best because of our loyal and committed members. I thank you for your support.

I finished my 6 months as a Chair of Orange Empire Section. I would like to provide highlights of last 6 months under different categories:

Lead by Example:

- Became ASQ Certified Biomedical Auditor (CBA) and Software Quality Engineer (CSQE). I value ASQ certifications and as a Chair, I wanted to earn certifications before I encourage our members to get one.

Responsiveness:

- All e-mails I received from our members were responded in maximum 24 hours.

Recognition:

- Recognized and honored Pat Nutchter, Carl Martin, and Dale Leuer for their valuable service as proctors for 1-3 years
- Recognized and honored Mark Lindsey, Dan Shibley, and Valerie Weed for their valuable service to generate the SCOPE for the past decade.
- Linda Garriz and Margaret Benavides for supporting our section to use the Alcon facility for refresher training and exams.
- Recognized Steve Peabody for his valuable service for the past many years to print and mail the SCOPE.

Leadership Committee

- Created a "VOC Representative" position to serve our members better

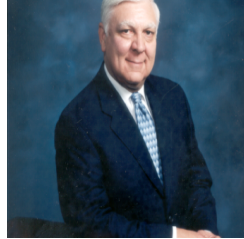
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January 13 Dinner Meeting

Doubletree Hotel, 201 E. MacArthur Blvd, Santa Ana
Directions: <http://maps.google.com/>



Please check our website for the dinner and clinic speaker for the January dinner meeting. At press time, the list of speakers were not available. However one of the highlights of the dinner will be honoring Dave Nagy for his extraordinary contributions to ASQ.



Continued from page 1

- Appointed Dale Leuer as a Vice Chair, Pritesh Patel as Career Chair, Ed Arpawong as Arrangement Chair, and David Vu as a VOC Representative (David previously held other LC positions).

Continuous Improvement

- Cut cost to eliminate paper version of the monthly publication SCOPE and convert it to electronic version. The goal was to cut cost, be environmentally friendly, and to include more articles. We have been consistently publishing more articles and valuable information in the eSCOPE.
- Allowed flexibility to Leadership Committee (LC) members to attend the monthly LC meeting by phone and hold in-person meeting once a quarter.
- Created and sent meeting agenda to LC members 3-5 days prior to the meeting.

I would like to add that our LC members voted in favor of several tasks listed above. I am fortunate to be surrounded and supported by highly skilled and dedicated leadership committee members. As a result, WE accomplished a lot as a team. When I became a Chair, my focus was: 1) Cost Savings, 2) Improving

member satisfaction, and 3) inspire the younger generation by increasing awareness of Quality field.

We completed cost savings project by eliminating paper version of the Scope and replaced it with electronic version. We are looking to be more efficient and to save money considering that we are a nonprofit organization. To improve member satisfaction, we created a “VOC Representative” position to receive and respond to feedback in timely fashion. We are open to feedback and making many changes to improve our member satisfaction.

I will be speaking with our LC team and Edwards management to give scholarship to high school students to recognize a graduating high school student with scholastic achievement and contributions to Quality. I strongly believe that our future is our younger generation. By inspiring younger generation to the field of quality, we will benefit the most in the future.

I would like to thank you for your continued support and I wish all of you have a great year.

Chairman – ASQ Section 0701
MSQA, MBA, B.S. (Chem), CQA, CSSBB, CQE, CBA, CSQE

HIGHLIGHTS FROM LAST MEETING

Over 40 Members & Guests attended the December 9th Dinner Meeting



Dave Nagy (Programs Chair) and Melanie Cummings (Past Section Chair) hosted the December 9th dinner meeting. To warm up the group before the dinner and special speaker, Margaret Benavides (Education Chair) & Dave Nagy each led a couple of fun team building exercises.



Richard Rumble was the keynote speaker whose presentation on hypnosis and self hypnosis techniques was informative and entertaining. Hypnosis has the potential for genuine positive effects not only in your personal life but also in your professional career.

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

If interested, please contact Lisa Bray at 414-298-8789 x 7545 or e-mail her at LBray@asq.org

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).

Announcements

You are invited to attend a 2-day Extensive, In-Depth Workshop on Design of Experiments.

To register for this workshop please go to <http://www.acteva.com/booking.cfm?bevaid=171307>

2-Day Extensive DOE Workshop and Training

Agenda

DATE: Saturdays, Jan 24th and Jan 31

TIME: 8:00 am - 5:00 pm

LOCATION: Conference Room CC6, SCAQMD, 21865 Copley Drive Diamond Bar, CA 91765-4182

Day 1 (Basic)

Design of Experiment Basics

- Terminology and Examples

Factorial Experiments

- Disadvantages of OFAAT

- Interactions

Planning & Preparing an Experiment

- Checklist and Communication

Fractional Factorial Designs

- Confounding

Analyzing an Experiment

- Effects Analysis

Screening Designs

- Plackett-Burman Designs

Day 2 (Advanced)

Response Surface Methodology

- Full Factorials with more than 2 Levels

Steepest Ascent Method

The Taguchi Approach

- Orthogonal Arrays

- Signal to Noise Ratio

Mixture Designs

- What is a Mixed Design

The Role of DOE in Process Validations

- Process Parameter Setting

DOE in the DEx (Design for Excellence) Process

Key Learning Points:

Analyzing many factors at the same time using DOE

Knowing the importance of Interactions

How to Evaluate a process in an organized way and report the information

Optimizing a process with current equipment

Early Bird Registration: Thru December 31st

ASQ Members: \$125.00

Non-Members: \$150.00

After Dec 31st:

ASQ Members: \$150.00

Non-Members: \$175.00

2.0 Ru's will be awarded for attending Both days of this training

Time: 8:00 am - 5:00 pm (with refreshment breaks and 1-hour lunch break). Water and sodas will be provided during breaks. Lunch-- on your own.

[Register Here](#)

ABOUT THE SPEAKER

Larry Bartkus was named ASQ Biomedical SCDG Speaker of the Year 2007-2008 for his informative and always humorous presentations. He is currently Supplier Quality Program Manager for ev3 in Irvine. He is a Certified Quality Engineer and Six Sigma Master Black Belt with over thirty years experience in the Quality profession. He holds a degree in Chemistry from Montclair State University in New Jersey. Larry has been guest speaker at the Society of Plastic Engineers, Society of Manufacturing Engineers, APICS, and ASQ. He is a past Chairmen of ASQ Section 702 and has served on the Executive Board for over twenty years now. He was an instructor for several CQE Refresher Courses and has conducted seminars in Process Control, Statistical Sampling, and Design of Experiments.

Sign up here on Acteva: <http://www.acteva.com/booking.cfm?bevaid=171307>

For Questions about this event, please contact Kandy Senthilmaran at 517-290-6663 or e-mail at kanthassamy@hotmail.com

Leadership Team 2008

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Secretary

Luke Foo
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Treasurer

Vinay Goyal
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Arrangements Chair

Ed Arpawong
E-mail: asq0701@cox.net

Publicity/Internet Chair

Joanne Pettigrew
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E-mail: pettijo@voughtaircraft.com

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E-mail: Hillbillie9@aol.com

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E-mail: jdhuwalia@jdconsulting.com

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ASQ Regional Director, Region 7

Holly Duckworth
E-mail: duckworthha@cox.net

SCOPE Editor

Daniel Shibley
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



Brian A. Bui
Denny S. Bui
Patricia J. Cabaldon
Frank J. Del Valle
Osvaldo A. Fior
Hadj D. Garcia
Brian G. Green
Robert Maciel
Viral J. Patel
Frank Pucci
Fred Strader
Tiffany Tolen

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

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.

Career Corner

Dear Members:

These are tough times, especially if you have been recently laid-off and are looking for work. Here is an article I found with some helpful resume-writing tips. In today’s market, you need every slight edge you can get. Click on this link:

<http://www.wikihow.com/Avoid-Common-Resume-Mistakes>

- Pritesh Patel
- Career Chair

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 .				

Upcoming Certification Courses



CQA - Biomedical Exam Prep Course

Exam Date: March 7, 2009. Exam application deadline: January 16, 2009

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

Course fee: \$400 plus cost of textbooks. Scholarships are available - contact Education Chair.

Time: 6:00 pm - 9:00pm. 3.3 RU's will be given for this course.

Session/Dates: 11 sessions total: Wednesdays from January 14, 2009 to March 25, 2009.

Will Cover: Will cover: Food, Drug, & Cosmetic Act, Quality System Regulation, Medical Device Directive, ISO 9000:2000, ISO 13485, Audit Requirements, QSIT, Domestic and International Standards and Guidelines, Sterilization, Biocompatibility, Environmental Control, Software, Laboratory testing, etc. Also covers strategies/tips for preparing & taking the exam

Reference Books: The Biomedical Quality Auditor Handbook, ASQ Quality Press (Order #H1171). Member Price - \$66.15; List Price - \$ 110.25

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition (e-book). Member price - \$57.00; List price - \$95.00

Arter, Dennis R., Quality Audits for Improved Performance, 3rd ed., ASQ Quality Press, 2003 (Order #H1180) (or any quality system audit textbook as reference)

Instructors: various instructors based on their expertise.

Enrollment: Open through January 21, 2009

Certified Manager of Quality/Organizational Excellence Exam Prep

Exam Date: March 7, 2009. Exam application deadline: January 16, 2009

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

Course fee: \$400 plus cost of textbooks. Scholarships are available - contact Education Chair.

Time: 6:00 pm - 9:00pm. 3.0 RU's will be given for this course.

Session/Dates: 9 sessions total: Mondays from January 5, 2009 to March 2, 2009.

Will Cover: Leadership, Strategy Development & Deployment, Quality Management Tools, Customer Focused Organizations, Supplier Performance, Management, & Training/Development. Plus, strategies/tips for preparing & taking the exam.

Reference Books: Certified Quality Manager of Quality/Organizational Excellence Handbook (Required). CQM/OE Handbook \$63.00 available from ASQ Quality Press at <http://qualitypress.asq.org> Item#H1264 or call 800-248-1946.

The Memory Jogger II (Recommended - Pocket Guide of Quality & Planning Tools). The Memory Jogger II \$10.95 available from GoalQPC at <http://www.goalqpc.com> or call 800-643-4316.

Students to purchase prior to class.

Instructors: TBD.

Enrollment: Open through January 19, 2009

Upcoming Certification Courses

CQI / CQT Exam Prep Course

Exam Date: March 7, 2009. Exam application deadline: January 16, 2009

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

Course fee: \$400 plus cost of textbooks. Scholarships are available - contact Education Chair.

Time: 6:00 pm - 9:00pm. 3.0 RU's will be given for this course.

Session/Dates: 10 sessions total: Mondays from January 5, 2009 to March 2, 2009, plus one class TBD.

Will Cover: Inspection & Test techniques and Methods, Metrology, Calibration, GD&T, Basic Statistics, Statistical Process Control, Capability Analysis, Acceptance Sampling, etc. Also covers strategies/tips for preparing & taking the exam (One additional class TBD)

Reference Books: Quality Council of Indiana CQI or CQT Primer, Latest Edition with solutions (Required). \$100.00 for either CQI or CQT Primer/Solution Text, to be purchased by the student directly through the Quality Council of Indiana at 1-800-660-4215 or at www.qualitycouncil.com.

Griffith, Quality Technician's Handbook, Latest Ed. (Recommended).

Students to purchase prior to class.

Instructors: Aaron Reddoch (Aaron.Reddoch@Landsberg.com) and Vinay Goyal (VinayGoyal@sbcglobal.net) and Linda Garriz (Linda.Garriz@AlconLabs.com).

Enrollment: Open through January 19, 2009

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>



Letter from the Editor:

In this months Scope, we feature a primer on Hypothesis Testing from Pritesh Patel, Director of Quality at

Allergan, and for those who missed the November meeting, we present again a recap of the clinic given by Ed Matthews on some Best Practices for Quality professionals.

*Dan Shibley
– E- Scope editor.*

Hypothesis Testing

By

Pritesh Patel, MBA, ASQ CQE, CMQ/OE

There are two different types of statistics; descriptive statistics and inferential statistics.

Descriptive statistics look at a process, and describes the process in statistical terms as as mean, variation, kurtosis, normality. We can use descriptive statistics to make conclusions about the process itself. As example is to derive a 95% confidence interval or determine the upper and lower control limits to determine stability of the process.

Inferential statistics looks at two or more data sets and makes inferences about the two sets. One common tool used is hypothesis testing.

This article looks at hypothesis testings for different statistical tools and provides a handy table to interpret the different hypothesis. This article will

not look at the statistics behind the hypothesis testing, but only in understanding what the hypothesis means for each tool.

When setting up a hypothesis test, there are only two hypotheses that need to be set. The first is the null hypothesis (H_0) and alternate hypothesis (H_1 or H_a). We can choose to either reject or fail to reject the null hypothesis based upon the statistically derived p-value and comparing that with the α risk that we have decided to take. The default for the α risk is 0.05 or 5%.

If the derived p-value is less than the α -risk, we reject the null hypothesis for the alternate hypothesis. If the p-value is greater than the α -risk, then we fail to reject the null hypothesis, and accept the null hypothesis.

It's feasible, that given any statistical test that generates a p-value, we can either accept or fail to accept the null hypothesis. But what does that mean? It can get confusing to understand what the null and alternate hypothesis is for the common statistical tests out there.

From my experience I have put together the following definitions of the null and alternate hypothesis for common tests when using Minitab statistical software.

- **Normal Probability Test**
 H_0 : Data are Normal
 H_1 : Data are not normal
- **Anderson-Darling Test for Normality**
 H_0 : Data are Normal
 H_1 : Data are not normal
- **t-test**
 H_0 : The mean of the sample distribution is the same as the reference mean
 H_1 : The means are not the equal

- **One way ANOVA Table**
 H_0 : There is no difference between the means

H_1 : At least one mean is different from the others

- **Two way ANOVA Table**
 H_0 : There is no difference between the means

H_1 : At least one mean is different from the others

- **Balanced ANOVA Table**
 H_0 : The factor has no effect on the Response
 H_1 : The factor does have a effect on the Response

- **Moods Median Test or Kruskal-Wallis Test (Non Parametric)**
 H_0 : The Medians are equal
 H_1 : At least one median is different form the others

- **Chi - Square**
 H_0 : There is no relationship between the variables
 H_1 : There is a relationship between the variables

- **Correlation**
 H_0 : There is no correlation between the variables
 H_1 : There is a correlation between the variables

- **Regression Analysis**
 - **Top Table**
 H_0 : Coefficient is equal to zero
 H_1 : Coefficient is not equal to zero
 - **Bottom Table**
 H_0 : All coefficients, except b_0 are equal to zero

H_1 : All coefficients are not equal to zero.

- **Homogeneity of Variances (using F-Test or Bartlett's Test for normal data or Levene's test for non normal data)**
 H_0 : Variances are equal
 H_1 : At least one variance is different from the others.

- Pritesh Patel

Generic Templates – Best Practice for Busy Quality Professionals

For those who could not attend Clinic #2 at the November 9th monthly section meeting, I want to share several key points that Ed Matthews (Quality Leader & Lean Expert at Honeywell International) discussed with the group. The purpose of this article is not to recount his fine presentation as these few words can't do justice to his excellent materials, shared insights and the group dynamics. My purpose is to use this one clinic as an example of:

1. the high quality and relevance of the monthly section clinics and dinner speakers,
2. valuable handouts – PowerPoint summary notes and/or templates usable for and adaptable to your occupational needs.

Several important topics and professional recommendations were covered. Among them were:

1. the origin and use of the A3 Management Process contained in 7 steps;
2. critical project information (i.e. solving problems, evaluation of proposals, implementing change, continuous improvements) captured on one piece of paper useable for planning, status updates and final reports;
3. functional usefulness of generic templates as a Lean tool in process improvement and organizational communication.

1. A3 refers to the size of the paper (11" by 17") on which the seven steps of the process flow are concisely presented in a standard format. For

many years, Toyota Production System has utilized the A3 as a best practice embedded in its 4 P's of lean production (Philosophy, Process, People & Partners, and Problem solving) in order to focus on the lean process fundamentals and to report the major findings. The A3 form with graphics and brief explanations is the foundation of a concise, visually compelling report. The potential issue with A3 is the typical office environment may not have direct access or network link to an A3 capable printer.

2. Due to increased information flow within organizations and workplace demands, long winded emails and/or word documents can be boring and may not be effective in promoting effective internal communication and discussion. The A3 process focuses the participants on the process and a systems thinking approach to proposals and project. First, it is an excellent planning tool by showing the current condition. Secondly, it can function as status reports for recording key process data, analysis, proposed countermeasures, implementation and control methods. Finally, it can be utilized as the final report form to summarize the activity and success of the project.

3. Ed Matthews shared how Honeywell has adopted the A3 and similar templates as a best practice. Honeywell staff was spending as much as three hours on average creating new project forms. By modifying generic templates available on their corporate database, staff time was reduced to less than one hour when creating new project flowcharts and reports. As a result, generic templates reduce waste/increase productivity...

To view some of the Ed's clinic resource materials, visit our section website at www.asqorangeempire.com On the homepage, click on the link "*Ed Matthews – Learning to Solve*

Problems". Review the 10 files. Download those that may have value to you. If you don't already have a "template" folder, create a new folder as a step in forming your own best practice. Promote your professional and teamwork capabilities through the efficient use of templates in your systematic planning and investigation into solving a complex problem and reporting the key factors & countermeasures.

At a minimum, please consider attending our valuable monthly clinics and dinner meetings. There is no charge for members for the clinics and ASQ recertification units (RU) can be earned. Looking forward to seeing you and sharing our professional experiences at future clinics and dinner meeting. Happy New Year - may 2009 bring you many opportunities. Thank you for your membership and participation!

Dale Leuer
Section 0701 Vice Chair



Meet the Leadership Team

Meet the Leadership Team will be a regular feature article for the year 2009. This month we feature Jack Dhuwalia, our section Membership chair. Jack brings a wealth of knowledge, experience, and moments of levity to the Leadership team.

Jack Dhuwalia, M.S.ChE, MBA, DTM

Membership Chair Section 0701

Jack is an expert trouble-shooter specializing in the medical industry. He has been problem-solving in R&D, manufacturing and quality areas. Since 1992, he co-founded JD Consulting, a firm specializing in medical industry.

Jack specializes in design control, risk management, root cause analysis and CAPA. He teaches classes for UCI in medical products life-cycle management. He is a guest lecturer at USC on quality and regulatory issues. He has published several articles on CAPA, problem solving, productivity and communication. He has spoken on Root Cause Analysis and CAPA during FDA-OCRA events. He enjoys sharing his knowledge and public speaking.

He is a past member of the executive board of OCRA, a professional organization for quality/regulatory affairs.

He may be contacted by calling 949-854-4534 or by email at jdhuwalia@jdconsultingsite.com



If you ever greet him on an airplane, don't ever shout "Hi Jack!". You might get arrested!



Congratulations to 31 Members (Section 0701) who passed the 10/18/2008 certifications tests.

**Certified Manager of Quality/
Organizational Excellence (11)**

Arellano, Jesus Z.
Bhakta, Savita
Brendle, Robert
Chiu, Darlene G.
Demartino, Tammy D.
Hedayati, Azita
Kasavan, Desmond A.
Patel, Pritesh
Shivers, Howard D.
Van Dorp, Holger R.
Varney, Lorne R.

Certified Six Sigma Black Belts (10)

Balbuena, Mike S.
Donohue, John Scott
Hoffman, Kevin A.
Lalor, David P.
Maxfield, Mari A.
Mullens, Thomas
Nadolny, Blake
Sanchez, Fernando
Strokosz, Arek
Zheng, Kevin

Certified Biomedical Auditor (4)

Espinosa, Marcelo
Gomarooni, Faranak
Mehta, Bhavan V.
Nitollama, Joni

Certified Quality Inspector (4)

Hernandez, David
Marmolejo, Antonio
Nardone, Fred
Sedaka, Jack

Certified Quality Technician (2)

Feldman, Edward
Strong, Lorrie A.

CONGRATULATIONS

Career Opportunities

Director of Regulatory Affairs – DRA-SFV

San Fernando Valley, CA

Description:

Direct the regulatory affairs specialists in the preparation of submissions to obtain and maintain approvals for conducting clinical investigations and for commercially distributing products worldwide.

Responsibilities: Generate or direct regulatory affairs specialists in the preparation of submissions (i.e. PMA, 510(k), PMA supplements, CE marking applications, product registrations, etc.) to obtain various worldwide approvals to commercially distribute products. Oversee the subsequent submissions (annual reports, change notifications, etc.) to facilitate the maintenance of these approvals. In conjunction with Clinical Research, prepare or direct regulatory affairs specialists in the generation of applications (i.e. IDE) for conducting clinical investigations in U.S., Canada and EU countries

Education/Experience: B.S. in scientific discipline or engineering. 10 – 15 years of experience in the area of worldwide regulatory affairs at medical device companies. Previous supervisory experience required. Experience in a Class III device manufacturing environment is a plus.

Regulatory Affairs Manager

San Fernando Valley, CA

Prepare submissions to obtain and maintain approvals for conducting clinical investigations and for commercially distributing products worldwide.

Responsibilities:

Champion worldwide submissions and compliance activities,

Prepare regulatory applications, Act as primary interface with FDA, registrars and other regulatory bodies in order to obtain and maintain approvals to perform clinical evaluations of products

Experience/ Requirements: B.S. in scientific discipline or engineering 5+ years related experience and/or training in FDA regulatory affairs and clinical research or equivalent combination of education and experience. Experience writing RA submissions, IDE an PMA a plus RAC certification is a plus.

Senior Quality Engineer

Orange County, CA

Class III Medical Device Company

Responsibilities:

Provide Quality Engineering support and leadership to ensure the successful development of products and design assurance. Identifies and manages risk throughout the development process with the use of FMECA and/or other risk management tools.

Provides input to design and manufacturing documentation including material specifications, drawings, inspection procedures, and manufacturing procedures, to ensure that the resulting products can be adequately manufactured and tested. Designs and installs quality process sampling systems, procedures and statistical techniques.

Assures compliance to FDA, ISO and internal Quality Standards for product development and manufacturing. Conducts training and supervises other engineers and inspection personnel on Quality tasks.

Education/Experience:

BS degree in Engineering, Physical or Life Sciences. 5 years of Quality Assurance experience in the medical device industry.

Regulatory Affairs Specialist

Orange County, CA

Class III Medical Device Company

Responsibilities:

Product dossiers and submissions for domestic and international regulatory affairs.

510K , PMA and International submissions and approvals. Direct interaction with FDA, foreign regulatory agencies, and distributors. Post market regulatory for domestic and international product approvals. ISO and FDA export requirements. Review Engineering Change Orders.

Education/Experience:

Bachelor's degree in Biomedical Engineering or Equivalent.

2-3 years of US medical device regulatory submission/approval experience.

510(k) submissions experience required, PMA submissions experience preferred.

Domestic and international device regulatory submissions a plus. Knowledge of FDA and EU requirements.

Senior Regulatory Affairs Specialist

Los Angeles, CA

Prepare and maintain 510(k), IDE, PMA submissions, supplements, and annual reports to obtain and maintain approvals for conducting clinical investigations and for commercially distributing products worldwide.

Experience/ Requirements:

B.S. in scientific discipline or engineering.

A minimum of 3-5 years of worldwide medical device regulatory experience.

Experience writing RA submissions. Class II and Class III medical device R & D and manufacturing experience is a plus.

RAPS certification is a plus.

For inquiries of these positions, please contact: Cheryl Jones

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Email: recruiter@medexecintl.com Web: <http://www.medexecintl.com>

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