

# SCOPE



The Official Newsletter of the ASQ Orange Empire Section

September 2011

## Section Chair Column - ASQ Letter from the Chair



Welcome to another addition of our e-Scope. We hope you find the information contained within this issue informative.

As promised at the August dinner meeting. I am providing the web link where you can download the presentation materials from the 2011 ASQWCCI.

<http://wcqi.asq.org/2011/index.html>

Best Regards,

***Ed Matthews, MBA, CMQ&OE, CSSBB, Lean Master***

***Chairman ASQ Section 0701***

As I mentioned in August our Financial Audit of our accounts was completed on July 19th, 2011. We received confirmation from ASQ National that it has been accepted and meets the requirements set by ASQ. A copy of the Audit will be available for members to review during the next 60 days at our monthly business meeting.

Our new web site should be in place by the beginning of September and you may be reading this from our new web site.

As members of ASQ we receive a monthly members appreciation gift. The gifts provide information and tools that we can use. I have found that the short training sessions have provided an excellent tool for lunch and learn sessions where I work. Keep an eye for the opportunity to download your free member gifts.

## September 13 Dinner Meeting

Doubletree Hotel, 201 E. MacArthur Blvd, Santa Ana



5:45pm Clinic # 1, **Joshua Gray** presents *Using*

**FMEA to Assess Risk**. As we strive to better understand and mitigate the risks in our business, we need to become proficient at tools & techniques available to assess risk.

Failure Mode & Effects

Analysis (FMEA) is a proven method to help you uncover the potential risks that you face. Using FMEA, you will be able to clearly identify the points of risk in your business processes and systems, and be able to develop strategies to ensure those risks don't disable your operation. Once identified, risks can be mitigated and their probability of occurrence can be decreased. Using FMEA, you will gain insight into the perils that can impede your company's success, and will stay one step ahead in the battle to mitigate risk.

5:45pm Clinic # 2, **Margaret Benavides** presents *"Soft Skills for the Hard Skills Quality Professional"*. Using the concepts of the Leadership Compass, identify the different types of leading one chooses to follow. In this highly interactive program, participants will gain insight

into their position on the team, contributions from others, and how to develop an action plan for improvement. By participating in this clinic, you will:

- Map your personal work-style and the work styles of a team.
- Understand the motivations and work-style of colleagues.

At 7:30 pm, the dinner topic **Dave Nagy** presents **CHANGE AND TRANSITION MANAGEMENT**. Any organizational initiative that creates change has a 70% chance of NOT achieving what was originally envisaged. There is a significant difference between change and transition. Often the ink is not dry on one change initiative before the organization embarks on another initiative, and that is likely not to stop any time soon. If the organization wants to get it right and avoid the 70% failure rate, they need to manage the change (initiative) and the transition (people) equally. Transition is the other half of the equation. Transition is the internal, psychological process that people go through to come to terms with the new situation. It is about "buy-in," acceptance, getting on board. During this program, we will:

- Discuss the difference between change and transition
- Examine the reasons why there is a 70% organizational failure rate
- Look at the Bridges and Lewin change transition model
- Develop a "make it stick" change and transition plan



As a principal of Bolero Associates LLC, **Dave Nagy'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. Clients include National Oilwell Varco, Flowserve Pump, Raytheon RTS, Rockwell Collins, Medtronic, Toyota, and Goodwill Industries. As a retired director from Hallmark Cards, Dave 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.



**Margaret Benavides** is the Education Chair for Section 0701 and is a consultant improving systems and processes for the biomedical companies in Orange County, California. Graduating with honors, she received a B.S. in Material Science Engineering from San Jose State University and has an extensive background in quality engineering and process improvements in commercial, aerospace, and medical device industries. She has received many quality, cost, and cross-functional improvement awards serving such diverse organizations as General Electric, IBM, Boy Scouts of America, Thales, Brunswick, & Alcon. She is an ASQ Certified Quality Engineer, Auditor, Biomedical Auditor, and Six Sigma Black Belt and specializes in audit/gap analysis, CAPA/root cause analysis, Lean/SPC, and Validation services.

**Joshua Gray** is an Associate Consultant for Enterey, Inc., a consulting firm headquartered in Irvine, CA, specializing in Quality and Operations for the Life Sciences, and President of JLG Consulting, Inc. Mr. Gray earned his Six Sigma Black Belt while working at General Electric, and is also certified as a Project Management Professional. Mr. Gray's experience spans the Biotechnology, Defense, Energy, Finance, Healthcare, Insurance, Real Estate, and Transportation industries, working as a Project Manager and Process Improvement consultant. Most recently he has consulted with a leading biotechnology company and the Department of the Treasury, providing project management leadership and leading process improvement initiatives.

Picture Not Provided

## Leadership Team 2011

### Chair

Ed Matthews  
C: (714) 686-6638  
E-mail: [Ed.Matthews@Honeywell.com](mailto:Ed.Matthews@Honeywell.com)

### Vice Chair

Annette Ant  
C: (949) 903-3274  
E-mail: [anetteant@hotmail.com](mailto:anetteant@hotmail.com)

### Secretary

Laurie Patton  
E-mail: [laurie.patton@cox.net](mailto:laurie.patton@cox.net)

### Treasurer

Bob Olevson  
C: (714) 394-4883  
E-mail: [bob@olevson.com](mailto:bob@olevson.com)

### Programs Chair

Dave Nagy  
W: (714) 883-9305  
E-mail: [daven@boleroassociates.com](mailto:daven@boleroassociates.com)

### Volunteer Audit Chair

Dale Becker  
E-mail: [trquality2@msn.com](mailto:trquality2@msn.com)

### Career Chair

Sharon Dalmage  
E-mail: [sdalmage@gmail.com](mailto:sdalmage@gmail.com)  
Phone: (714) 808-4575

### Arrangements Chair

Ed Arpawong  
E-mail: [asq0701@cox.net](mailto:asq0701@cox.net)

### Publicity/Internet Chair

Steve Martin  
W: 714- 985-3022  
E-mail: [smartin@bbspecialties.com](mailto:smartin@bbspecialties.com)

### Education Chair

Margaret Benavides  
W: (714) 654-2479  
E-mail: [qamargaret@gmail.com](mailto:qamargaret@gmail.com)

### Certification/Renewals

Karen Gaynor  
W: (949) 753- 6248  
E-mail: [Karen.Gaynor@AlconLabs.com](mailto:Karen.Gaynor@AlconLabs.com)

### Examiner

Hassan Farah  
C: 909-261-3517  
[E-mail: hfarahasq@gmail.com](mailto:hfarahasq@gmail.com)

### Financial Auditing Chair

Darrell Moyer  
H: (562) 795-5990  
E-mail: [darrellmoyer@sbcglobal.net](mailto:darrellmoyer@sbcglobal.net)

### Nominating Chair

Don Shannon  
E-mail: [don\\_shannon@cox.net](mailto:don_shannon@cox.net)

### Deputy Regional Director

Vinay Goyal  
W: (714) 876-3927  
E-mail: [vinaygoyal@sbcglobal.net](mailto:vinaygoyal@sbcglobal.net)

### Membership Chair

Vinay Goyal  
W: (714) 876-3927  
E-mail: [vinaygoyal@sbcglobal.net](mailto:vinaygoyal@sbcglobal.net)

### Outreach Chair

Bob Mehta  
W: 949-510-9138  
E-mail: [bobasq0701@gmail.com](mailto:bobasq0701@gmail.com)

### ASQ Regional Director, Region 7

Elias Monreal  
E-mail: [emonreal@itde.com](mailto:emonreal@itde.com)

### SCOPE Editor

Luke Foo  
W: (949) 743-9208  
E-mail: [Luke.Foo@sppirx.com](mailto:Luke.Foo@sppirx.com)

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

## Welcome New Members



Chris Alliro  
Ali Altaha  
James M. Arganda  
Kevin Doan  
Alissa A. Enriquez  
Todd C. Farquhar  
Cyrus R. Galvan

Eric G. Gardner  
Michael Graber  
Nancy A. Haase  
Michael C. Harris  
Raphael T. Hon  
Ramy Khalil  
Robert Kunesh  
Mike Leggett  
Yi Chun F. Liu  
Mike Lopez  
Brian R. McCarthy  
Suzanne Mcconn  
Calin Melen  
Santiago Monsalve  
Carlos A. Moz  
Tom J. Nauman  
Jon Pierce  
Daina Quon  
John M. Rubio  
Natalie E. Ryther  
Alan Lee Sands  
Fuad Paul Sarhangnejad

Jitendra Sata  
Janhavi Turkar  
Renee J. Van Dorne  
Mario J. Vesnaver  
Chung-Chih Wang  
Samuel Yoon

**All new members are eligible for free admission to a dinner meeting within 3 months of becoming a member. Please contact Vinay Goyal for a free voucher at [vinaygoyal@sbcglobal.net](mailto:vinaygoyal@sbcglobal.net)**

\*\*\*\*\*

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](mailto:help@asq.org)

## Bolero Associates, LLC

[www.boleroassociates.com](http://www.boleroassociates.com) 714-634-4441



*Dave Nagy, Principal*

Bolero Associates, a consulting company focused on increasing productivity, improving processes, and improving the bottom

line for our clients.

- QMS ISO 9001:2000, AS9100, and TL 9000
- Team Problem Solving and Decision Making
- Change Management - Achieve your vision
- Innovative Supply Chain Solutions
- Communication Development
- Leadership Development
- Baldrige & CA Quality Strategy Deployment

## Assure Your Competitive Excellence

Get the leading-edge professional development you need with Cal State Fullerton's wide range of certificate programs.

Areas of focus include:

- Business Intelligence
- Engineering
- Green and Sustainability
- Information Systems
- HR & Leadership
- Project Management
- Six Sigma
- Custom Workforce Solutions
- ...and much more!

[www.CSUFextension.org/quality](http://www.CSUFextension.org/quality)



CALIFORNIA STATE UNIVERSITY, FULLERTON  
University Extended Education

### Mail Recertification Packages to:

*Alcon Laboratories*

*Attn: Karen Gaynor QADC*

*15800 Alton Parkway, Mail-stop 145, Irvine, CA 92618*

Course	Next Exam Prep Start Date	Exam Dates	Application Deadline
CQI/CQT	Jul 27, 2011	Oct. 1, 2011	Aug. 12, 2011
CSQE	Sep 21, 2011	Dec 3, 2011	Oct 14, 2011

**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.

# The Industry's Trusted Medical Device Design & Manufacturing Resource Comes to a Computer Near You!

## What is MD&M Online?

MD&M Online is an Internet-based conference and exposition dedicated to medical device design and development. It gathers medtech manufacturing professionals and the industry's leading medical OEM suppliers together in an online environment to create a dynamic interactive experience – [from the convenience of your desktop](#).

## MD&M Online brings valuable resources directly to you

Medical device design and manufacturing professionals will gain complete access to the resources they need to accelerate their active projects to market.

Simply log onto a computer and take advantage of all that MD&M Online has to offer:

- No travel time or expenses, and no time out of the office
- Live and On-demand conference sessions
- Video demonstrations featuring leading-edge technology
- Informative white papers
- Dozens of technology presentations
- Valuable networking opportunities through private and group chat sessions
- e-Brochures
- Giveaways... *and much more!*

## For Visitors

- [Preview MD&M Online](#)
- [REGISTER](#)
- [Add a reminder to your calendar](#)
- [See who's exhibiting](#)
- [Contact us with any questions about visiting](#)

## Exhibiting Opportunities

- [Preview MD&M Online](#)
- [Learn more about exhibiting](#)
- [Event Prospectus](#)
- [Questions about the event or booking a booth?](#)
- [Schedule an appointment](#)

***Stepping Up & Stepping Out!***

# QUALITY DAY 2011 October 28

Join us for a full day Quality Conference providing you with opportunities to gain the confidence to step out of your comfort zone and into new challenges, skills, and visibility to advance your quality knowledge and raise the bar on delivering customer satisfaction. This event will feature two nationally recognized keynote speakers along with three 90-minute presentations from the track of your choice. In addition to a total of five presentations, a continental breakfast and a sit-down lunch will also be served. A HUGE value for the price, as a gift to the section members and the local quality community.

*Choose from these 3 Tracks:*

Track #1: Teams/ Quality Management

Track #2: Career

Track #3: Supplier Quality

Where: Doubletree Santa Ana/Orange County Airport 201 East MacArthur Blvd. Santa Ana, CA 92707

Cost: \$45 ASQ Section 0701 Members \$55 Non-Members

**7:00 -8:00**

**Registration/Continental Breakfast**

**8:00- 9:00**

**Keynote Speaker - Rob Bryant**

**9:00- 9:15**

**Networking Break**

**9:15-10:45**

**Track Workshop #1**

**10:45- 11:00**

**Networking Break**

**11:00-12:30**

**Track Workshop #2**

**1:15-2:15**

**Keynote Speaker - Chris Alexander**

**2:15-2:30**

**Networking Break**

**2:30-4:00**

**Track Workshop #3**

**4:00-4:15**

**Closing**

# QUALITY DAY 2011 October 28, 2011

## Keynote Speakers

### **Imagine, Believe and Achieve - The Keys to Stepping Up and Stepping Out! - Chris Alexander**



The quality of our lives is measured by the determination we possess to direct and inspire ourselves and others to achieve a shared destiny- a clearly defined, pre-determined vision. Imagination is where the seeds of greatness are sown and where the power of belief begins. Behind every strongly held belief is a burning desire that leads to inspired continuous actions, resulting in a sense of fulfillment and purpose.

#### **Participant Take-aways:**

This presentation is based on 3 realities of success:

1. The ability to inspire ourselves and others by clearly defining a pre-determined vision.
2. The power of purpose, desire and belief.
3. The self-determination to go into action and become victorious by pushing through procrastination, fear and doubt.



### **Employee Engagement and Its Effect on Lean/Six Sigma Performance and Customer Satisfaction**

#### **- Rob Bryant**

Lean/Six Sigma is most effective with senior leadership sponsorship, well chosen projects, well chosen personnel and employee engagement. In 10 companies surveyed with high employee engagement, they outperformed their five largest peers during 2003 by 26% in gross margins, and by 85% in sales growth. Employee engagement leads to customer engagement. For all kinds of companies, fully engaged customers deliver a 23% premium over the average customer in:

- Share of wallet
- Profitability
- Revenue
- Relationship growth

Actively disengaged customers represent a 13% discount (decrease) on the same measures. Within a given company, business units whose levels of customer engagement are in the top 25% tend to outperform all other units by a factor of 2:1

# QUALITY DAY 2011

## Workshop Presenters

### **A Deeper Look at the Six Stages of Quality System Implementation**

**- Dr. Phil Rosenkrantz**



The ability of an organization to effectively implement continuous improvement or quality management systems requires the transformation from a transactional culture to a transformational culture. Understanding the subtle differences between these two cultures is essential to leading the transformation. The focus of the presentation will be to model the differences in these two cultures using Hayes' Six Stages of Quality System Implementation and show how this model aligns well with many current leadership philosophies and actually ties them together. This understanding is very useful for those involved in leading the change process.

### **Managing Supplier Purchasing Control – GHTF Guidance SG3/N17:2008**

**- Bob Mehta**



The FDA regulations for medical devices define the requirements for supplier selection, management, and control. ISO 13485 and ISO 9001 include similar requirements. The Global Harmonization Task Force (GHTF) released a guidance document on controlling products and services from suppliers in six phases.

Supply chains for medical devices are growing in importance as device manufacturers outsource products and services. As some of this outsourcing moves offshore and to low cost countries, the supply chain becomes longer, more diverse, and more difficult to control. The medical device manufacturer, however, has the ultimate responsibility for the product. As a result, manufacturers must have all aspects of the supply chain compliant. The presentation will help you understand the expectations of the GHTF guidance document.

### **Supplier Risk is Ever Present - A review of industry trends, regulations, and risk management activities in two highly regulated industries: Aerospace & Pharmaceutical**

**- Daniella Picciotti**



Risk is a key factor in all industries. There are many avenues where suppliers contribute to the risks each company faces. Various industries are developing standards and guidelines to mitigate and manage supplier risk. Companies are using these standards to deploy or expand supplier management and monitoring processes as a means to reduce the impact of supplier risk. This session will overview some examples of supplier risk and the approaches to managing that risk in two regulated industries: aerospace and pharmaceutical.

# QUALITY DAY 2011

## Workshop Presenters

### **Attention to Quality Principles Can Positively Impact Productivity In The Evolving Multigenerational Workplace**

**- Rosemarie Christopher**

Embracing the generational differences of each of the four generations in the workplace can increase productivity through continuous learning of each diverse characteristics and incremental improvement of practice. Participant Takeaways:

- Understanding the characteristics of the four generations in the workplace
- Tools to effectively increase the productivity of the new diverse workforce

---

### **CREATE A STELLAR JOB SEARCH PLAN WITH THE TOP 45 JOB SEARCH TECHNIQUES**

**- Heather Wieshlow**

Job seekers must choose from a complex array of job search techniques in order to find a job in today's highly competitive market; yet often have little knowledge on how to effectively navigate through the various options available to them. Bottom line, every hour not employed is money that is lost forever. By gaining a deep understanding the various techniques available to professionals it becomes much easier to create an effective a Job Search Plan with clients. In this presentation, participants will gain a wealth of information and tools to help them create plans that that are focused, encourage productive results and are manageable.

---

### **Quality in Data Visualization**

**- Michael Scofield**



You can't "do" quality without measuring processes and outcomes.

Generally, the more data points the better, but intuitively grasping a large amount of data in a tabular form is nearly impossible for most of us. This is why charting becomes so important. But incorrectly created, charts can be misleading.

After reviewing the data-to-information life cycle, we will look at techniques to convert tabular data into meaningful information which appeals to the human eye-brain combination. The ultimate goal is to create in the mind of a decision-maker a clear understanding of reality and the processes and outcomes. In addition to the basic charting techniques, we will look at some advanced methods.

---

### **Design of Experiments Simplified**

**- Linda Howe Garriz**

"If you do not expect the unexpected, you will not find it." -Heraclitus



In this 1 ½ hour clinic, we will learn the basics of the most power methods to better understand and characterize processes - the two-level factorial and fractional factorial experimental designs.

You will learn the basics of how to define and set up a factorial designed experiment and a fractional factorial screening experiment. We will then use this knowledge to work through several case studies to understand the application of these techniques to solve real-world problems.

# QUALITY DAY 2011 Program

Time	General Session	Track # 1 Quality & Management	Track # 2 Career	Track # 3 Supplier Quality
7:00 AM	Registration / Contential Breakfast			
8:00 AM	General Session - Keynote Rob Bryant "Employee Engagement and its effect on Lean/Six Sigma Performance and Customer Satisfaction"			
9:00 AM	Break & move to 1st Workshop			
9:15 AM	Workshop # 1	Dr. Phillip R. Rosenkrantz - "A Deeper Look at the Six Stages of Quality System Implementation."	Heather Weishlow - "Create a Stellar Job Search Plan with the TOP 45 Job Search Techniques"	Bob Mehta / "Six Phases of Supplier Control" - Managing Supplier Purchasing Control – GHTF Guidance SG3/ N17:2008
10:45 AM	Break & move to 2nd Workshop			
11:00 AM	Workshop # 2	Michael Scofield / Quality in Data Visualization and Information Delivery	Rosemarie Christopher - "How attention to Quality principles can positively impact productivity"	"Dani Picciotti / Raytheon -- "Supplier Risk is Ever Present"  Aerospace & Pharmaceuticals
12:30 PM	Sit down lunch / General Session room			
1:15 AM	General Session - Keynote Chris Alexander and "Imagine, Believe and Achieve - The Keys to Stepping Up and Stepping Out!"			
2:15 AM	Break & move to 2nd Workshop			
2:30 AM	Workshop # 3	Linda Howe Garriz / Simplified DOE for Quality Improvement	John Hall / Career Transition	Mark Lindsey / Supplier Assessment
4:00 AM	Closing			
4:15 AM	End Time & clean-up			



**Worldwide services for  
the Pharmaceutical,  
Medical Device, Biologics,  
Diagnostics and Biotech  
industries**

Clinical Research  
Regulatory Affairs  
Quality Assurance & Compliance  
Medical Affairs



800.507.5277 | www.meirrs.com | info@meirrs.com  
100 N. Brand Blvd | Suite 306 | Glendale | CA | 91203

# FULL SERVICE DIMENSIONAL MEASUREMENT LAB

Since 1987



*For Your Product's Perfection*

- Dimensional Inspection
- Reverse Engineering
- 3D Scanning



**MEASUREMENT RESULTS YOU CAN  
COUNT ON WHEN YOU NEED THEM!**

**Q-PLUS Irvine**  
Tel : 949-380-7758  
Fax: 949-380-7790  
sales@qpluslabs.com  
www.qpluslabs.com

**Q-PLUS** offers vast  
measurement capabilities  
and complete solutions.  
Call or email for a quote!

ISO 9001  
REGISTERED  
ISO 17025  
ACCREDITED



**Premium Services at Lowest Prices / Fast Turn-Around**

## eScope 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: Luke Foo 949-743-9208 or [luke.foo@sppirx.com](mailto:luke.foo@sppirx.com)

*Congratulations to the following members who have sent in their recertification packages:*

Shayan Babibi
Jennifer Hansen
Luyanti Loh
Sue Knight
Juan Carlos Baldi
Gail A Benard
Walter J. Zenda

**PROFESSIONAL DEVELOPMENT COURSES**

- QUALITY ASSURANCE FOR MEDICAL DEVICES
- A+ CERTIFICATION PREP
- PROJECT MANAGEMENT
- ACCOUNTING



**School of Continuing Education**  
North Orange County Community College District  
*Change. Cultivated.*



**WWW.SCE.EDU**  
**714-808-4915**

ISO 9001 REGISTERED ISO 17025 ACCREDITED  
ACCREDITED Certificate No. 2275 01  
REGISTERED COMPANY NO. 981-288 COURT NO. 188

*Premium Services at Lowest Prices / Fast Turn-Around*

*Congratulations!*

**Richard Clark** has won the drawing for a free dinner at the monthly ASQ meeting held at the Doubletree Hotel every 2nd Tuesday at each month. Please join us at the next meeting, and you too may win a chance for a free dinner!

**Upcoming ASQ Event - Mark Your Calendars!**

**ASQ Orange Empire Quality Day**  
**October 28, 2011**  
An entire day filled with quality

# Job Opportunities!!!

## Quality Director Salt Lake City, UT

**Industry** - Class I & II Medical Devices

**Department:** Quality and Regulatory

### Essential Duties and Responsibilities, other duties may be assigned:

- Develop and maintain sustainable Quality System meeting FDA requirements
- Analyze process and product non-conformances and implement corrective actions
- Ensure corporate good documentation practices
- Knowledgeable in 21 CFR Part 820 for medical devices
- Develop and support a team environment and professional conduct
- Develop methods of measurement to allow for the objective benchmarking improving quality
- Analyze processes and systems to create continuous process improvements through measurement, analysis and improvement plans

### Education and Experience requirements

- 5 years Medical Device experience in QA systems management, engineering, and compliance
- Knowledge of development and manufacturing of Class I & Class II Medical Device products
- Good working knowledge of all subsystems of 21 CFR Part 820 (including complaint handling, CAPA, Nonconforming products, change control and design)
- Experience with regulatory bodies and inspections required

- Face to Face experience with and FDA inspection auditor answering questions from the inspector about a Quality System
- Good working knowledge 510(k) submission and registration
- ASQ CQE, CQA, or CQM are a plus
- Supplier Quality experience preferred
- Ability to perform a variety of office tasks at a high level of proficiency
- Demonstrate computer skills in spreadsheets, word processing and email

## Sr. Quality Process Engineer Santa Barbara, CA

**Department:** Quality  
**Reports To:** Director of RA/QA

### Essential Duties and Responsibilities, other duties may be assigned:

- Plastics Injections molding
- Blue print reading and GD&T
- Validation for the design of plastics
- Gage R&R/Statistical Process Control
- Make up QC instructions for plastics

### Education and Experience

- BS/BA Engineering, science/technical field
- 5 years related experience/working knowledge of 21CFR 820 ISO13485, 14971 and MDD
- Validation protocols, SOPs and guidance documents
- Metrology
- American Society for Quality CQE (Certified Quality Engineer) preferred

## Regulatory Specialist Los Angeles, CA

**Department:** Regulatory Affairs  
**Reports To:** Regulatory Affairs Manager

### Responsibilities:

- Support IVD documentation for pre IDEs, 510(k)s, PMAs and BLAs to FDA and Health Canada
- In vitro Diagnostic product performance study review
- Supplier and clinical study management
- Review domestic and international guidance documents to update company of any new regulatory requirements
- Act as regulatory department representative interact both internally (Quality, R&D, etc) and externally (suppliers, distributors, etc.)
- 510(k) electronic submissions
- Regulatory SOPs
- Other duties may be assigned

### Education and Experience

- BS/BA in one of the Life Sciences, Health Care or other related field
- Proven track record of regulatory in the biologics, blood banking and/or in-vitro diagnostics industries
- FDA and Clinical Laboratory Standards Institute (CLSI) standards
- Ability to review statistical performance data with statistical software (such as Analyse-It)

Please contact:

**Lewie Casey**

**Talent Manager, Recruitment & Retention Manager**

**MEIRxRs, Med Exec International & RxResearch Staffing**

**100 North Brand Blvd., Suite 306, Glendale, CA 91203**

**Phone: 818-552-4173**

**Email: [lcasey@medexecintl.com](mailto:lcasey@medexecintl.com)**

**Web: <http://www.meirxrs.com>**



## *From the desk of the Section Membership Chair – Vinay Goyal*

Please mark your calendar for the following important section events

- ✓ **2<sup>nd</sup> Tuesday of each month – Monthly dinner meeting\* preceded by clinics**
- ✓ **Friday October 28, 2011 – Quality Day\* – whole day event**

\* DoubleTree Hotel 201 E McArthur Blvd, Santa Ana, CA 92702

**We will be sending out event invitation and registration link soon via email.**

We sincerely apologize that the reconstruction of our section website was taking longer than expected. It will be up with current information soon. Thank you for your emails, phone calls for bringing it to our attention. It was crashed due to unknown reason over a month ago.

We need help from our members to get the word out to our section. If you can help in recruiting one member from your company, client, or class etc we can double our membership and can improve our worldwide ranking from 4<sup>th</sup> to 2<sup>nd</sup> or 3<sup>rd</sup> and hopefully one day to 1<sup>st</sup>.

Have you noticed that ASQ website has changed? If not, please take a few minutes of your time to browse ASQ website at: [www.asq.org](http://www.asq.org)

Enter your email address or log in ID, and Password to access some information only available to members and member leaders. However, to learn about the certification programs, joining ASQ, contacting customer service etc, does not require you to be a member or to have a log-in ID or password.

If you ever wonder, the difference between Certificate and Certification is, please go to ASQ website [www.asq.org](http://www.asq.org) or click on this link <http://www.asq.org/media-room/news/2011/03/20110309-certificates-vs-certification.html>



While browsing ASQ website, I noticed on Paul Borawski's (Current CEO ASQ) blog, an interview (a series of brief video clips) with Dr. J.J. Irani of Tata Sons, a leading company based in India. I really enjoyed watching this interview and hope you would find it interesting as a quality professional

<http://asq.org/blog/2011/07/four-questions-creating-a-culture-of-quality-with-dr-j-j-irani/>

If you have any questions, please feel free to contact any of our section leadership committee (SLC) members or myself.

Thank you,

***Vinay Goyal***  
***Membership, Booster and VOC Chair***  
***Deputy Regional Director 2011-2012***  
***ASQ Section 0701 Orange Empire***