

SCOPE



The Official Newsletter of the ASQ Orange Empire Section

December 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.

I hope everyone had a happy Thanksgiving holiday. As we approach the holidays in December on behalf of the Section Leadership Committee I want to wish everyone a happy holiday season and a joyous New Year.

I want to also remind everyone that information on ASQ Certification and recertifications is located on the main page of our section web site. One of the rotating banners provides detailed information on where to send your recertification packages. There is also information on how to prepare for new certifications.

We also want to recognize those individuals who recently (October) pass their certification exams. Congratulations on achieving a new milestone.

Best Regards,

Ed

*Ed Matthews, MBA, Lean Master, CMQ&OE, & CSSBB
Chairman ASQ Section 0701*

December 13 Social Event

Doubletree Hotel, 201 E. MacArthur Blvd,
Santa Ana

A Magical Evening with David Chen and Juan Zeval

David Chen has been entralling audiences with his breathtaking illusions and His special brand of magic has won him celebrity within the Chinese community where he has performed at numerous community events feature magician for wedding, grand opening and festive occasions. Chen is well-known throughout all of southern California and is a much requested presence at personal and commercial events. He is the member of Hollywood Magic Castle.



Juan Zeval is a well known magician member of Hollywood Magic Castle, has perform numerous times in the Magic Castle, companies event, Wedding, Birthday and TV program. His special brand of magic is walk around close up magic with fun and entertaining all ages.

THE EVENING:

5:30 p.m. Registration

5:45 – 6:30 – Hors d'Oeuvres & socializing

6:30 – 7:30 p.m. Dinner

7:30 p.m. – 9:00 – A Magical Evening show

- The show schedule is as follow:

- 7:30 to 8:20 Walk around (close up magic)
- 8:20 to 8:35 stage magic (dove act)
- 8:40 to 9:00 Interactive magic (will invite audience on the stage) Fun show.

9:00 p.m. – final announcements and close

Hotel Information: Doubletree Hotel Santa Ana/Orange County Airport

201 East MacArthur Boulevard (on corner of MacArthur Blvd and Imperial Promenade)

Santa Ana, CA 92707

Tel: (714) 825-3333

- **Cost for ASQ Section 0701 Members AND ALL of their family and guest**
 - \$30 with RSVP before Early RSVP Deadline includes Hors d'Oeuvres, dinner meal, and the Magical Evening Presentation.
 - \$40 at the door includes Hors d'Oeuvres, dinner meal, and the Magical Evening Presentation.
- **Cost for all others:**
 - \$45 with RSVP before Early RSVP Deadline includes Hors d'Oeuvres, dinner meal, and the Magical Evening Presentation.
 - \$55 at the door includes Hors d'Oeuvres, dinner meal, and the Magical Evening Presentation.

Sorry, but there will NOT be a "free" clinic only option for this event.

Leadership Team 2011

Chair

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

Vice Chair

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

Secretary

Laurie Patton
E-mail: laurie.patton@cox.net

Treasurer

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

Programs Chair

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

Volunteer Audit Chair

Dale Becker
E-mail: trquality2@msn.com

Career Chair

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

Arrangements Chair

Briana Sallows
E-mail: briana.sallows@gmail.com

Publicity/Internet Chair

Steve Martin
W: 714- 985-3022
E-mail: smartin@bbspecialties.com

Education Chair

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

Certification/Renewals

Karen Gaynor
W: (949) 753- 6248
E-mail: 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

Nominating Chair

Don Shannon
E-mail: don_shannon@cox.net

Deputy Regional Director

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

Membership Chair

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

Outreach Chair

Bob Mehta
W: 949-510-9138
E-mail: bobasq0701@gmail.com

ASQ Regional Director, Region 7

Elias Monreal
E-mail: emonreal@itde.com

SCOPE Editor

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

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

Welcome New Members



Dragos Agafitei
Christopher Alexander
Teresa O. Avendano
Socorro R. Baldonado
Jonathan Bartilad
Mark Basinger
Teri Beauchamp

April Bonner
Shomik Chaudhuri
Ritesh Reddy
Chintakuntla
Timothy B. Cole
Mark G. Condell
Aimee Denike
Andrew P. Dunn
Daniel C. Eagles
John Espy
Joshua Fadriquetla
Rhett E. Falls
Keith Garrison
Doug B. Hillman
Anna Hoang
Lili Hong
Mohan Janardhanaiah
Ashish Jani
Jacob Kearns
Charles Kim
Thomas L. Kindberg
Elizabeth Kotowski

Rukhsana Lalani
Lori Lang
Phelisha Licerio
Bryan Mark
Huy Nguyen
Raymond L. Plows
Anthony A. Ramirez
Cathy Rimm
Rob Robson
Bhavesh Ronvelia
Anupma Seth
Derek G. So
Jack Sowin
John Z. Sun
Joleen A. Valentine
Phong T. Vo
Kirk V. Walberg
Kenneth J. West
Christopher Williams
Kim Winders
Yi Young

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

Bolero Associates, LLC

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



CALIFORNIA STATE UNIVERSITY, FULLERTON
University Extended Education

7822-4

Mail Recertification Packages to:

Alcon Laboratories


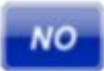
Attn: Karen Gaynor QADC

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

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.

Announcements

Dear Members,

Any time you receive email/invitation for section events, you have a choice to register by clicking on  or decline by clicking on .

If you do not choose either one, you will keep receiving anytime a reminder goes out.

You also have a choice not to receive **any section** emails/invitations by simply clicking on “**Opt-Out**” at the bottom of the email invitation. **See example below.**

Having trouble with the link? Simply copy and paste the entire address listed below into your web browser: http://www.cvent.com/d/pZAdpBjDtEyrkdSE5d4z8Q/97vm/P1/10? If you no longer want to receive emails from Vinay Goyal please click the link below. Opt-Out

Please note: If you choose to opt-out, you would STOP receiving any further section event related emails/reminders.

If you do not want to receive email from ASQ HQ, please either change your profile on-line, or by calling customer care at 1-800-248-1946 (M-F: 7:00 am to 5:00 pm Central Time)

If you have any questions, or need further clarification, please feel free to contact me.

Vinay Goyal

vinaygoyal@sbcglobal.net

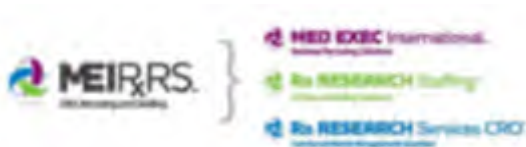
Membership Chair 2011-2012

ASQ Section 0701 – Orange Empire



**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.meirxrs.com | info@meirxrs.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

*Mention this
ad for 5% off*

**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

Congratulations on Becoming Certified!

Certified Biomedical Auditor

Katie M. Blackwell
Jay Garcia
Louise M. Miyamoto
Brenton Parks
Ken B. Racen
Robin Templin
Janhavi Turkar
Renee J. Van Dorne

Certified HACCP Auditor

Jack C. Dhuwalia
Rowena R. Herrella
Sid Poonawala
Caroline Trillo
Hiroyuki Tsukiji

Certified Quality Technician

Aimee Limberg

Certified Reliability Engineer

Paul Aquino

Certified Quality Inspector

Mark Brantner
Don Cline
Peter P. Manliguez
Jay B. Mehta
Adam Vandenberg

Certified Six Sigma Black Belt

Diggy Breiling
Robert Brendle
Azman Hanipah
David C. Kohl
Qi Liu
Sergey Lymar
Tony Martinez
Thomas V. Towey
Tracey Tsuma

Manager of Quality/Organizational Excellence

Todd Banville
Scott A. Edwards
Alissa A. Enriquez
Bryan Gray
Kerry A. Gwin
Susanne E. Hernandez
Lester E. Oestreich
Philip Peralta
Ernest J. Schrepfer
Marlene G. Swider

Congratulations!

Michael Rhodes 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!

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

ASQ
REGISTERED
ISO 13025
ACCREDITED



Premium Services at Lowest Prices / Fast Turn-Around



EDUCATION



Certified Quality Inspector / Quality Technician Refresher Course

SESSIONS/DATES

9 sessions total; 7 sessions Tuesdays Nov 29, 2011 to Jan 31, 2012 at NOCCCD, 2 session on Feb 7 and Feb 14, 2012 at Alcon Labs Irvine and 1 session On-line TBD from 6-9 PM (No class on Dec 20, 27 and Jan 3)

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

On-line Course - You can attend from anywhere as long as you have computer, internet connectivity and a phone line

Certified Quality Inspector / Quality Technician Refresher Course

SESSIONS/DATES

9 On-Line sessions total: Saturdays from 9:00 am to 11:30 am on Dec (2011) - Dec 3, Dec 10, Dec 17, Jan (2012) - Jan 14, Jan 21, Jan 28, Feb (2012) - Feb 4, Feb 11, Feb 18

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

Fees

Employed Member Fee \$400.00 for a limited time (\$500.00 original price)

Nonmember Fee \$450.00 for a limited time (\$500.00 original price)

Unemployed Member Fee \$300.00 for a limited time (\$400.00 original price)

On-line Registration <http://www.cvent.com/d/dcqmjd/10>

Questions: Call Vinay Goyal (714)-876-3927

When:

Tuesday, November 29, 2011 - Tuesday, February 14, 2012 6:00 - 9:00 PM (Pacific Time)

Location

North Orange County Community College, 1830 W. Romneya Drive, Anaheim, CA 92801 USA

Fees

Course Registration

Fee \$350.00 Before November 21, 2011 (After Nov 21, 2011 : \$400.00)

Unemployed Member Fee \$200.00 (with proof)

On-line Registration <http://www.cvent.com/d/7cqm4y/4W>

Questions: Call Vinay Goyal (714)-876-3927 or email: vinaygoyal@sbcglobal.net

Train with the best.

Take your career further with a professional continuing education certificate from UC Irvine Extension. We offer the most practical, convenient, and cost-effective training available.



PROGRAMS OF INTEREST:

- Regulatory Affairs 
- Medical Product Development 
- Clinical Trials: Medical Device & Drug Development 
- Embedded Systems Engineering 
- Communications Systems Engineering 
- Optical Engineering and Optical Instrument Design
- Project Management 
- Business Analyst 
- Six Sigma Lean


FALL COURSE HIGHLIGHTS:

- Introduction to Lens Design
- Optical Systems Design
- Medical Product Marketing
- Six Sigma Lean Project Management
- Regulatory Requirements For Medical Devices
- Clinical Data Management
- Medical Product Life Cycle Management

ASQ members receive 10% discount on course fees. Use discount code ASQ10 when enrolling.*

extension.uci.edu
(949) 824-5414

UCIRVINE | EXTENSION

 online program
*valid for programs and courses listed in this ad only.

OPERATIONAL EXCELLENCE CONSULTING



"We provide world-class, customized Operational Excellence Solutions that enable our clients to achieve best-in-class performance and realize sustainable business improvements."

- Operations Development
- Strategy Deployment & Hoshin Planning
- Performance Management & Balanced Scorecard
- Lean Six Sigma Training & Implementation
- Business Process Improvements
- High Performance Work Teams
- Customer Satisfaction Surveys

Please contact us to discuss how Operational Excellence Consulting can support you and your organization in establishing your own Operational Excellence initiative.

Frank Adler, Principal & Managing Partner

Website: www.operational-excellence-consulting.com

Email: info@operational-excellence-consulting.com

Phone: +1 (909) 319 - 1184

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

Keywords: Management of FDA audits, answering questions from an FDA Inspector, Quality Systems expertise, leader

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

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

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

