Boulder Section 1313
ASQ AMERICAN SOCIETY FOR QUALITY

The next ASQ Boulder Section meeting will be held on Thurs, Jan 27th at the Quantum R&D Bldg with tutorial start at 5:30pm and the main talk at approx 6:20pm. Please see page 3 for more details.

Volume 17, Issue 6 **Jan - Feb 2011**

JANUARY CHAIR MESSAGE

Steve Jobs wisely stated, "Your time is limited so don't waste it living someone else's life. Don't be trapped by the dogma – which is living with the results of other people's thinking. Don't let the noise of other's opinions drown out your own inner voice. And most important, have the courage to follow your heart and intuition. They somehow already know what you truly want to become. Everything else is secondary."

The US Department of Labor's Bureau of Labor Statistics published a report on 7th January 2011 showing the unemployment rate falling by 0.4% to 9.4% in December 2010. Though this rate is greater than two years earlier, it is a sign that there is job growth. Applying the words of Steve Jobs and also performing a personal inventory concerning your career path, this is a good time of year to ask yourself, "Am I in the right place for me and for my career?" How do you know? The first step, according to Kouzes and Posner in "The Leadership Challenge", is to clarify your values. You have to comprehend fully the deeply held beliefs that drive you. You have to freely and honestly choose the principles that you will use to guide your decisions and actions. Then you have to genuinely express yourself.

I realize that many of our current section members are in a position of career transition at this time. Remember that whether you are in a position where you are looking for work, looking for a new opportunity, or simply considering your current position, the first step is to be clear about who you are and what you value. Data supports that you will have a higher level of commitment to your employer and a greater level of job satisfaction if you first clarify your values and, assuming your company clarifies it's values, and if your values align well with the company values.

Yes, you may be technically qualified for multiple positions. Will you be happy and committed to your employer if your values do not align? To act with integrity, you must first know who you are. You must know what you stand for, what you believe in, and what you care most about. Clarity of values will give you the confidence to make the tough decisions, to act with determination, and to take charge of your life, as well as your career.

Don't waste your time living someone else's life.

Sincerely, Rebecca Jessep ASQ Section 1313 Chair

ASQ'S Customer and Member Center:

E-MAIL: help@asq.org

PHONE: 800-248-1946
FAX: 414-272-1734
USPS MAIL: ASQ Communications
600 N. Plankinton Ave.
Milwaukee, WI 53201-3005

We suggest that you go to the ASQ National web site at: **www.asq.org** for complete ASQ national news, regional event links, books, courses, yearly certification testing, re-certifications, conferences, ASQ Divisions and on-line membership forms, including member upgrades and what is needed to update your own member profile. And, while you are on the internet, be sure to visit **ASQ Boulder Section website** at: **www.asq1313.org**

Did You Know? ASQ Divisions and Sections offer approx. 70 scholarships, some of which go untapped due to limited number of student applicants.

Quality Association of Denver (SQuAD) Conference (Mar 9-10, 2011)

Conference information:
http://www.squadco.com/conference.html
Registration site
http://www.eventbrite.com/event/903986849
Cost: Early Bird Registration: $299
After Jan 31, 2011: $369
Boulder Section contact person: Arnold Miller (arn_miller@earthlink.net)

ASQ National News

An ASQ Founding Member Passes Away

E. B. "Oz" Godsey was a founding member of ASQ, passed away December 20. One of the first ASQ Certified Quality Engineers (CQE), Godsey was active in the local, regional, and national levels of ASQ for 63 years.

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ASQ #1313 Officers & Committee Chairs 2009-10

ASQ Section 1313	Boulder, CO		
Title: Chair Name: Rebecca Jessep Phone: 303-587-7067 E-mail : rebeccajessep@hotmail.com	**Title: Vice Chair** Name: Joe Wojniak Phone: 303-530-6581 E-Mail: joe.wojniak@yahoo.com	**Title: Newsletter Editor** Name: Gerry Naugle Phone: 303-591-2830 e-mail gnaugle@earthlink.net	**Title: SMP** Name: Mike Ferraro Phone: 720-684-2035 E-mail: michael.a.ferraro@seagate.com
Title: Secretary Name: Melinda Schones Phone : 303-359-5531 E-mail: mschones2002@yahoo.com	**Title: Treasurer** Name: Ewald Schelert Phone: 303-702-9009 E-mail: Schelert@mesanetworks.net	**Title: Certification** Name: Wells Lange Phone: 303-604-6694 E-mail: wellspolly@comcast.net	**Title: Programs** Name: Guy Harris Phone: 303-470-7020 E-Mail: harrisgb@comcast.net
Title: Re-Cert Name: Larry Derouin Phone: 303-431-9287 E-Mail: LWDerouin@comcast.net	**Title: Internet & Website** Name: Arnold Miller Phone: 303-466-2631 E-Mail: arn_miller@earthlink.net		
Title: Publicity and VOC Name: Byron Murray e-mail: byron.murray@yahoo.com	**Title: New Members** Name: e-mail:		
Title: Financial Auditing Name: Wells Lange Phone: 303-604-6694 wellspolly@comcast.net	**Title: Education Chair** Name: John Beachman Phone: 303-530-6346 e-mail: john.beachman@covidien.com		

Upcoming ASQ #1313 Tutorial & Main Presenters as of: Jan 14th, 2011

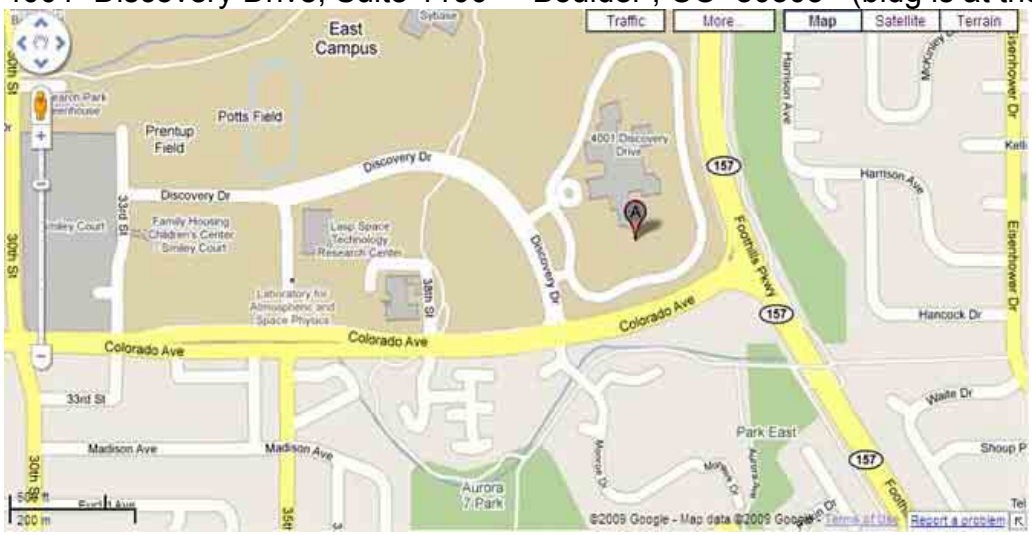
All Boulder Section tutorials start at 5:30pm on the 4th Thurs of each month, except where the date or any other aspect of the meeting is denoted in **bold blue font**.

January 27th

Main Talk: Gary Deniston, Covidien/Boulder, on *Risk Management in the Medical Device Industry.*

30-Min Tutorial: Jayaprakash (JP) Gnanam, *Why Lean Six Sigma Implementations Fail*

The January ASQ meeting will be at Quantum Corp / Boulder Research Park facility
4001 Discovery Drive, Suite 1100 Boulder , CO 80303 (bldg is at the A" indicated below)



ASQ Meeting attendees should park on the North side and enter through the main building doors on the North-East side. (Note: These are not the Quantum doors but doors to the main building. If any problems, use: 303-587-7067 as the contact for the meeting.

Coming up in April:
Joint ASQ Meeting with the Denver Section start at 5:45 PM - Wednesday, April 20th, 2011
Hotel VQ - 1975 Mile High Stadium Circle (http://www.asqdenver.org/HotelVq.htm)
Meeting and Meal Costs Buffet: $15 RSVP deadline - Friday, April 15th, 2011

RSVP Options: You may RSVP for the meeting in any of three ways, as follow;
*You may RSVP by email to Arta Doci, Denver Section Program Chair (artadoci@gmail.com).
*RSVP by email to our Section Chair, Terra Stern (Terra.Stern@ssdglobal.net)
*RSVP to our new section voice mail at 303-571-9306
Just show up at the door. We will be happy to welcome you.

MBNQA
For info on the Malcolm Baldrige National Quality Award Program, visit www.quality.nist.gov
CPEx
For info on the Colorado Performance Excellence Program (Colorado State quality and business performance program), visit www.coloradoexcellence.org
Contact: Executive Director, Mr.Tom Mauro tmmauro@coloradoexcellence.org (or) at: 303-893-2739
Please see page 19 of this newsletter for the most recent information on upcoming 2011 CPEx activities and events. **The Boulder ASQ Section is a sponsor of the Colorado CPEx Organization.**

ASQ National News

continued from page 1

Join ASQ at the **19th Annual International Conference on ISO 9000 & QMS** in San Antonio, TX, **March 13–15, 2011.** This is the world's leading conference on ISO 9000 and related standards. We offer the most current and comprehensive technical program, as well as the best networking opportunities for our attendees.

Early-bird Discount
Take advantage of the early-bird rate on this conference! If you register by **February 4, 2011,** you will **save $50** on the conference price. You must sign up with code **ASQ5** to receive this special rate. Don't miss out on this event. See you in Texas!

19h Annual International Conference on ISO 9000
March 13–15, 2011
San Antonio, TX
The International Conference on ISO 9000, organized in association with ASQ, is a content-rich event. For nearly two decades it continues to be the leading conference on ISO 9000 and related standards.
Conference Workshops: March 13, 2011 **Conference Technical Sessions:** March 14–15, 2011

Benefits of Attending

For 2011, we offer the most current and comprehensive technical program, as well as the best networking opportunities for our attendees. This year the conference will feature presentations on a variety of business sustainability issues, including:

- Industry Benchmarking
- Standards, Trends, and ISO Evolution
- Disciplined Problem Solving
- Customer Relationship Management
- Systems Planning
- Global Supply Chain Management and Improvement
- Managing for Problem Prevention
- Optimizing Operational Excellence
- Professional Development and Human Resource Management

U.S. Food Safety Bill Passed

ASQ Calls for Third-Party Assessment With Oversight

U.S. President Barack Obama signed the Food Safety Modernization Act into law Tuesday, January 5. The law responds to several food safety outbreaks in recent years by strengthening the authority of the U.S. Food and Drug Administration (FDA). ASQ, through the ASQ-ANSI National Accreditation Board (ANAB), has been active in educating legislators and FDA officials of the importance of accredited third-party conformity assessment with oversight. It is the goal of ASQ and ANAB to promote this successful model in the United States.

2011 Scholarship Application Now Available

The Inspection Division is pleased to announce that it has increased its annual scholarship level to **$3000**! This scholarship was created to help members, their family or friends defray the costs associated with college expenses. Scholarship funds will be dispersed to one or more deserving students in the Spring of 2011.

Applications can be downloaded from the ASQ Inspection Division web site:
http://www.asq.org/inspect/about/awards-inspect.html

Applications can also be obtained by contacting Jim Spichiger at jim.spichiger@alcatel-lucent.com
Applications must be postmarked no later than February 15, 2011.

2011 Chuck Carter Award for International Inspector of the Year

- Applications are now available for the 2011 Chuck Carter International Inspector of the Year Award! For over 35 years the Inspection Division has offered this award to provide recognition to "The Inspector". Any qualified individual who spends more than 50% of his or her time in inspection, test, audit, calibration, etc., functions to assure conformance to engineering, manufacturing, quality and customer standards or requirements, is eligible as a candidate to receive the award.
- Applications can be downloaded from the ASQ Inspection Division web site:
  http://www.asq.org/inspect/about/awards-inspect.html
- Applications can also be obtained by contacting Jim Spichiger at jim.spichiger@alcatel-lucent.com
- Applications must be postmarked no later than February 15, 2011.

Join ANSI–ASQ National Accreditation Board/ACLASS for the **Expanded Internal Auditor** course in San Francisco, CA, January 24–28, 2011.

If you are an internal auditor in an accredited lab environment looking to conduct thorough and successful audits to meet the requirements of the ISO standard and of their accredited body, this course is for you! Content of this course includes the entire internal auditor course and additional materials related to measurement uncertainty, plus the accreditation requirements for OEM and other contract labs which provide calibration and testing services along with discussion of terms such as MU, BMC, CMC and Z 540.

Don't miss out on this course! Space is limited. **Expanded Internal Auditor**
January 24–28, 2011
San Francisco, CA
ASQ Member Price: $850.00
List Price: $950.00 For more information on this course or to register **click here,** call **703-836-0025, ext. 208,** or send e-mail to **cdefilippis@anab-aclass.org.**

Course cancellation policy: If you wish to cancel your registration of this course and receive a full refund, you must cancel by January 10, 2011. Please call 703-836-0025, ext. 208, or send e-mail to cdefilippis@anab-aclass.org. ANSI–ASQ National Accreditation Board/ACLASS reserves the right to cancel/reschedule any event or change instructors. Please be advised that ANSI–ASQ National Accreditation Board/ACLASS is not responsible for airfare penalties or other travel expenses you may incur.

Updates to ASQ Recertification Journal

There are changes to the recertification journal categories, including more opportunities for RU credits, and the categories have been better de-fined to make recertifying easier. The 18 RU credit amount remains the same. To order a new journal, call the ASQ Customer Care at: 1-800-248-1946 and ask for item B0525.

Note: Existing certifications to ISO 9001:2000 will be invalid after November 14, 2010

Purchase the new ISO 9001:2008 standard today from ASQ!

Have you transitioned to ISO 9001:2008 yet? ASQ is your **official** source for the latest version of the ISO 9001 standard and all your ISO needs. This new standard will replace ANSI/ISO/ASQ 9001:2000 and applies to any size organization—small, medium, or large—and all types of organizations—private or public sector. Because you are an ASQ member, you can take advantage of member pricing! Purchase this new standard and:

- Manage your processes effectively
- Enhance customer satisfaction
- Meet customer and applicable statutory and regulatory requirements
- **Order the hardcopy or electronic version of the standard from ASQ today!**

Looking for more ISO solutions? ASQ is your one-stop shop for all your ISO needs. Visit www.asq.org/iso9001 today

ASQ Boulder Section News

USPS Correspondence Address for the Boulder ASQ Section:

ASQ Boulder Section
P.O. Box 21595
Boulder, CO 80308-4595
Note: All education & course registration materials should be sent to Section Education Chair (please see the last page of the education section)

Boulder Section's Charity Donation Program:

The Boulder Section exec board has approved a policy of donating to bonafide local charities at $100 per calendar quarter. If you have in mind a deserving local charity, please let a Section officer know about it at any monthly meeting (or) bring to the attention of the entire exec board on via a letter. Enclose any information in an envelope and send it to the section correspondence address (above) or bring any information about your charity and pass it on to any section officer at any monthly meeting. Suggestions for the 2Q of 2011 are being accepted at the present time.

Unemployment Program for Membership Available from ASQ

ASQ headquarters is offering resources for members who have encountered job loss. One benefit for those who want to retain their membership, but have difficulty renewing because they are currently unemployed,

are discounted membership dues. Participating members receive a discount on their membership renewal based on consecutive years of membership. Currently, membership dues are $129 for current Full (formerly Regular), Senior, and Fellow members. For more information, and to check out other resources available, visit http://work.asqquality.org.

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ASQ Denver Career Enhancement Workshop -Building Value In Your Professional Potential

Cutting-Edge Quality tools + Enhanced Professional Knowledge = Maximum Possibilities

ASQ Denver would like to invite quality and process improvement professionals to participate in our two-day workshop focusing on quality tools,
professional knowledge, and possible career paths in the quality field.

Workshop Schedule

Day One – Thursday February 24th, 2011				
8:30 AM 9:00 A M	Welcome and Opening Remarks – Dr. Terra Stern More			
9:00 AM 10:30 AM	Starting Your Own Consultancy More	Learn how to identify and capitalize on your area of expertise	Speaker Larry Stern, PhD.	President and Founder SSD Global
10:30 AM 10:45 AM	Break			
10:45 AM 12:00 PM	What Quality Professionals Should Know About Project Management More	Help secure and expand your role as a quality professional	Speaker Andy Rodriguez, PhD.	Principal, Star LLC and Star Systems,Inc.
12:15 PM 1:15 PM	Lunch Presentation – Quality Management Systems & Assurance (QMS&A) – Gary Vansuch – NREL			
1:30 PM 2:30 PM	How to Promote Yourself as a Quality Professional More	How to create a professional campaign to promote your skills and abilities in the quality profession	Speaker Deborah Petty	Advisor, Facilitator, Trainer, Coach
2:30 PM 2:45 PM	Afternoon Break and Networking			
2:45 PM 4:30 PM	How to Conduct a Kaizen Event More	Japanese for “Change for the Better” Learn about this powerful process improvement tool	Speaker David W. McGee	Director of Operations Process Improvement - Denver Public Schools
4:30 PM	After-Workshop Networking			
Day Two – Friday February 25th				
8:30 AM 9:00 AM	Welcome and Opening Remarks – Dr. Terra Stern			
9:00 AM 10:30 AM	Limits of Statistical Thinking in Quality Management	Review of statistical quality controls and their limitations	Speaker Peter Bryant	Professor of Management

	More			Science and Information Systems, Business School, CU Denver
10:30 AM 10:45 AM	Break			
10:45 AM 11:45 AM	5-S For Everyone More	Japanese workplace organizational methodology	Speaker Michael Booth	Manger, Global People & Development, Molson Coors
11:45 AM 12:45 PM	Lunch Session – Breakout Table Discussions – Choose from FEMA, VSM, or Control Charts			
1:00 PM 2:30 PM	Think Your Way Into Business More	The Synergy Between Preparation, Passion, and Relationships	Speaker Kevin King, MBA, PhD. (ABA)	Founder and CEO Transformation Point, Inc.
2:30 PM 2:45 PM	Afternoon Break and Networking			
2:45 PM 4:30 PM	Business Plan Development More	For people interested in starting or transitioning into their own business	Speaker Dawn Gregg	Associate Professor of Information Systems, CU Denver
4:30PM	After-Workshop Networking			
* Earn .6 re certification units for workshop attendance				

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ASQ BOULDER SECTION #1313 COURSE DESCRIPTIONS *Revised 01-14-2011*

1301 – CERTIFIED QUALITY ENGINEER (CQE) REVIEW

This is a refresher course for those preparing to take the ASQ Certification exam. This course is advanced and intense. The instructor has an excellent text specific to this course, which is provided at no additional cost. It is recommended the student bring a copy of Juran's Quality Handbook, 5th ed., which can be purchased for about $135 through ASQ but used copies can often be found for much less on the Internet. The students must bring their own calculator. For additional details or questions, contact the course instructor or the Section Education Chair (his contact information is on page 10).

1305 – CERTIFIED SOFTWARE QUALITY ENGINEER (CSQE) REVIEW

This is a refresher course to aid in your preparation for taking the ASQ Certification exam. The Certified Software Quality Engineer is a professional who has comprehensive understanding of software quality development and implementation, a thorough understanding of software inspection, testing, verification, and validation, and can implement software development and maintenance processes and methods. The exam requires you have minimum software testing or development experience and you must meet certain minimum requirements. Each student needs to purchase the latest edition of the CSQE Primer published by the Quality Council of Indiana (QCI) prior to the first class (cost is approximately $70). To order, contact QCI at 1-800-660-4215 or www.qualitycouncil.com. For additional details or questions, contact the course instructor or the Section Education Chair.

1322 – ASQ Exam BoK: Quality Concepts, Management and Leadership

This course covers the Body of Knowledge (BoK) any quality professional should know about quality. This covers the history of quality from philosophies to current day methodology. This course is a must for anyone pursuing ASQ Certification or seeking a professional quality career.

Cost includes materials fees

Prerequisites: None

Course Outline:

- Management and Leadership [Organization Structures; Strategic Planning, Team Processes]
- The Quality System [Quality Philosophies; System Models; Measuring Effectiveness]
- Customer Focus
- Supplier Chain Management
- Product and Process Design
- Product and Process Control
- Continuous Improvement
- Management Tools [The Seven Classic Quality Tools; Basic Management and Planning Tools; Process Improvement Tools; Innovation and Creativity Tools]

1323 – ASQ Exam BoK: Statistical Principles, Techniques and Applications

Learning the principles of statistics in an understandable way as well as practical applications in the workplace. From understanding variation to hypothesis testing to process capability studies -- this course covers it all. The course covers the Body of Knowledge (BoK) required for ASQ Certification Exams. This is also excellent for any quality professional seeking a core understanding of the quantitative methods used in any improvement strategy such as Six Sigma or Lean covers the history of quality from philosophies to current day methodology. This course is a must for anyone pursuing ASQ Certification or seeking a professional quality career.

Cost includes materials fees

Prerequisites: Ability to understand basic mathematical expressions would be useful as well as ability to use a hand-held calculator.

Course Outline:

- Descriptive Statistics [Measures of Location; Measures of Spread; Shape of Distribution; Normal distribution]
- Concepts of Probability
  Statistical Decision-making [Central Limit Theorem; Test of Hypothesis; Alpha and Beta Risks]
- Statistical Process Control (SPC)
- Analyzing Process Capability
- Design of Experiments (DOE) [Full Factorials; ANOVA Tables; Partial Factorials (Taguchi)]
- Relationship Between Variables
- Reliability Statistics

1324 – ASQ CQE Book of Knowledge (BoK) Review

This course is designed to help you properly prepare to take and pass the CQE examination. The objective of the course is to help you put together a study plan. An overview of the Body of Knowledge (BOK) covered by this exam will be given. Detail study of the BOK is the responsibility of the student. Included in this course are effective test taking strategies

Cost includes materials fees

Prerequisites: None; however, the following ASQ Boulder Section courses would help those needing more detail knowledge:

- 1322 - ASQ Exam BoK: Quality Concepts, Management and Leadership
- 1323 - ASQ Exam BoK: Statistical Principles, Techniques and Applications
- Also there are requirements to be able to take the CQE exam.

- See ASQ website http://www.asq.org/certification/quality-engineer/

Course Outline:

- How to gather reference material
- How to do a self assessment
- How to develop a study plan
- The Body of Knowledge [Management and Leadership; The Quality System; Product and Process Design; Product and Process Control; Continuous Improvement; Quantitative Methods and Tools]
- What to take to the exam
- Test taking strategies

INSTRUCTORS & COURSE DESCRIPTIONS: A list of instructor biographies and course descriptions can be found on the ASQ Boulder Section web site, http://www.asq1313.org/ **COURSES LOCATIONS**: Contact the ASQ Boulder Education Chair, John Beachman at: john.beachman@covidien.com or 303-530-6346 to see if the class you want can be made available in the Colorado Springs, Denver, Loveland or Ft. Collins area.

Winter 2010 ASQ Boulder Section Course Offerings

Updated 01-14-2011

Course Name	Instructor	Course Fee (1)	Exam Date	ASQ Exam Application Deadline	Course Dates & Times	Course Registration Deadline
1301 - Certified Quality Engineer (CQE) Review	Monrad Monsen 303-272-9612 Location: TBD	$400 members / $450 others				
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631 Location: TBD	$400 members / $450 others				
1322 - ASQ Exam BoK: Quality Concepts, Management and Leadership	Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD	$270 per student + $25 material = $295 Total				
1323 - ASQ Exam BoK: Statistical Principles, Techniques and Applications	Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD	$270 per student + $25 material = $295 Total				
1324 - ASQ CQE Book of Knowledge (Bok) Review	Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD	$135 per student + $15 material = $150 Total				

([1]) Course fee for ASQ or other professional society member/non-member. (2) Cost of primers, texts, work-books, etc. are not included and must be purchased by the student prior the first class. Contact the Boulder Education Chair, **John Beachman**, (his contact information below) for details. FOR INFORMATION UP-DATES, please go to the Boulder Section web page: http://www.asq1313.org/courses.html

If there is a class you need but is not listed above. We may be able to offer that class in the future.

COURSE REGISTRATION INFORMATION

You do not have to be a member of ASQ to attend a class however, members of ASQ and other professional societies receive a discount for classes. Local Quality professionals teach all classes in the Boulder/Longmont/ Broomfield area unless otherwise noted. We contact you at least two weeks in advance of the class start date for the exact location. Classes are typically held at a company that employs one of the students. You may nominate your company for hosting a class. Directions and registration confirmations are provided. Participants receive a certificate upon completion of the course. We need a minimum of about 4 - 5 students to hold a course and we reserve the right to cancel or postpone classes not having enough students. A full refund will be given if minimum class registration requirements are not met. If you cancel within two weeks prior to a class beginning you may not receive a refund.

ASQ CERTIFICATION REVIEW COURSES: These courses are intended as a refresher course for those preparing to take the ASQ Certification exam. These courses are typically not introductory and are intended for people with either academic and/or on the job experience. NOTE: Enrollment in a class DOES NOT enroll the student for the certification exam. The student is responsible for confirming exam dates and application deadlines with ASQ Headquarters. Qualification requirements for sitting for an exam and information regarding exam applications may be obtained by calling ASQ Headquarters at 1-800-248-1946 or go to http://www.asq.org

ASQ #1313 COURSE REGISTRATION FORM

Please complete the following information as thoroughly as possible. In case of a schedule change or cancellation, we really appreciate two phone numbers to contact you.

Student's Name: _____ ASQ Membership #: _____

or other Society and #: _____

Title: _____

Company Name: _____

Address: _____

_____

_____

Daytime phone: _____ Night time phone: _____

E-Mail: _____ or FAX:: _____

Course # and Name: _____

Course Start Date: _____

Course Fee: $_____(ASQ Member) $_____(Non-member)

Please enclose a check payable to "ASQ Boulder Section" and contact the Boulder Section Education Chair John Beachman at: **john.beachman@covidien.com** (or) 303-530-6346, to reserve your spot in the course that you want. Please send checks to the address below.

ASQ Section 1313 Education c/o Mr. John Beachman 2031 Amethyst Dr Longmont, CO 80504

GUARANTEE: If you pay for and take one of our ASQ Certification review courses and still fail the Certification Exam, you may retake the course for free as many times as you need. The instructor reserves the right to charge for course materials (e.g., handouts, etc.). Your ASQ section leadership is committed to meeting your quality-related education and certification needs. If you have any questions about a particular course, please contact the instructor or the Boulder Section Education Chair (contact information above).

Non-ASQ Boulder Section (or) Non-ASQ Denver Section Training Resources

From: the quality Catalyst Inc.

Happy 2011!
If you have any training needs this year, keep me in mind. I specialize in **Process-Based Audits, Six Sigma Statistics** and **ASQ Certification**. Also I provide training in the next wave of the quality movement, **Service Quality**. Look at the December 2010 issue of Quality Progress for my article on service quality.

Let me know how I can help you. Wishing you continued success in the New Year.
Ron Sedlock
the quality Catalyst
phone: 303-716-5873 or 303-587-9153 (cell)
www.thequalitycatalyst.com

Colorado Quality Executive Network (CQEN)

The next session of the Colorado Quality Executive Network (CQEN) will be held on Tuesday, January 18, 2011 from 1-5 pm at MillerCoors in Golden. The network is a group of top quality executives discussing and sharing current quality trends. Membership is by invitation only. If you have any questions, contact Ron Sedlock the quality Catalyst 303-716-5873 or 303-587-9153 (cell)

Quality Related Careers Job Postings

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We suggest that you frequently go to: www.nrel.gov use the employment link

ISO 9000 Internal Auditor Trainee

Cavendish Scott, Inc. is looking for a trainee internal auditor. This is a trainee position rather than one for a fully qualified auditor as we want to develop our new colleague in our unique philosophy and style.

Cavendish Scott is the industry leader in providing ISO management system consulting. We provide the most practical, business focused and ethical systems to meet our customers' needs.

The role includes conducting internal audits to ISO 9001 and other similar standards (AS 9100, 14001, 13485, 17025, etc.) for Cavendish Scott clients. Initially you will be part of an audit team and provided full support. You will be given comprehensive formal and on the job training and eventually you will audit independently and lead audit teams.

The role will allow development as a professional ISO auditor, fully and formally qualified and performing and leading audits in a variety of standards. It is hoped that you will also participate in the provision of ISO training courses and possibly present training classes independently.

The ideal candidate will be dynamic, self-motivated, well presented, a good communicator, capable of working alone, capable of individual development and free to travel easily for about 0-10 days per month. You will be familiar with Microsoft office and outlook email. You will probably be an ISO (or similar) internal auditor, possibly full time but possibly as an occasional auditor in addition to your other duties.

Remuneration includes a generous salary package, bonuses, health/dental/vision and 401k contributions. To apply please briefly outline your applicability to the above criteria in an email. Please briefly explain:

Your recent work history and salary requirements.
Your experience of and knowledge of ISO 9000 (or similar standards e.g. FDA)
Your auditing experience
Cavendish Scott, Inc.
apply@cavendishscott.com

Swan Valley Medical, Incorporated – Director of Quality & Regulatory Affairs

Swan Valley Medical, Incorporated has recently announced an opening for a Director of Quality & Regulatory Affairs. Swan Valley Medical is in the final stages of developing urological surgical instruments and has offices in Denver, Colorado and Bigfork, Montana. For further information about the company, visit the web site at: www.swanvalleymedical.com.
Swan Valley Medical currently utilizes outside consultants for both its regulatory and quality assurance functions. The Company's products will be manufactured primarily by U.S. based contract manufacturers.
Ideal candidates will have 8+ yeas of medical device quality experience including FDA, 510(k), and audit experience. International experience is desired. The Director of Quality & Regulatory Affairs will establish, oversee, and implement the quality system for the entire Company. This position is a member of Swan Valley Medical's executive management team and will report directly to the President of the Company, while working closely with the development team during the transfer of the Company's products into manufacturing. Relocation will not be offered for this position.

Responsibilities:

- Manage the company's outside consultants providing regulatory and quality services when outside services are required
- Oversee quality control of all incoming parts and instruments and receiving inspection of single-use devices.
- Manage/ monitor/ perform inspection of all incoming product, product components and product returns.
- Check engineering drawings prior to release.
- Quality Assurance inspection and documentation including keeping all equipment calibrated according to schedule and document accordingly.
- Manage and monitor MRB activities and disposition.
- Oversee quality system registration.
- Implement and advise revision of quality system.
- Manage and oversee all regulatory activities including US regulatory submissions for 510k, IDE's, PMA, international regulatory submission registrations and all other regulatory activities.
- Manage and oversee the product complaint/CAPA system.
- Coordinate quality and regulatory audits both internal and external.
- Support agency audits at all facilities and coordinate follow up activities.
- Support supplier audits and interface with supplier quality assurance and internal quality assurance personnel and monitor follow-up to audits.
- Work with other departments to schedule appropriate vendor/supplier audits, assist with implementing, prioritizing and closing audits.
- Coordinate audit activities/planning, supervise activities of internal audit teams, monitor audit calendar.
- Implement the company's 13485:2003 registration

Qualifications:

- Bachelor's Degree in a technical discipline, preferably in a life sciences or mechanical engineering field. Advanced degree preferred.
- Medical device knowledge including thorough understanding of FDA Quality System, ISO 13485 and the MDD is required. Knowledge of other international regulations (Canada, Australia, Japan, China) is desired.
- 8+ years of experience in a quality management environment within a medical device company.
- Experience with FDA 510(k), ISO Technical file and incident reporting\adverse events and recalls required.
- Previous managerial or supervisory skills required as this position will require supervision of others.

Note: This job description is not intended to be an exhaustive list of all duties, responsibilities or qualifications associated with this position.

Swan Valley Medical, Incorporated is an equal opportunity employer.

Interested candidates should submit a resume by 5 PM, Mountain Standard Time by January 15, 2011.

Resumes should be emailed to: Kathie Lapcevic, EA, at K.Lapcevic@SwanValleyMedical.com

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WalkMed Infusion LLC – Director of Quality & Regulatory Affairs

WalkMed Infusion LLC is hiring for the position of Director of Quality & Regulatory Affairs. WalkMed Infusion LLC is manufacturer of ambulatory and pole mounted infusion pumps located in Denver, Colorado. For further information about the company, visit the web site at: www.walkmed.net. Ideal candidates will have 10+ years of medical device Quality Assurance and Regulatory Affairs experience. . International regulatory experience is desired, as several of WalkMed Infusion's customers are outside the United States. The Director of Quality & Regulatory Affairs will oversee, maintain and update the quality system for the entire Company. This position will be a member of the WalkMed Infusion management team and will report directly to the General Manager, while working closely with the engineering, and manufacturing teams.

Responsibilities:

- Lead Quality Assurance and Regulatory Affairs functions for the company including effective implementation of the Quality System.
- Implement and advise revision of quality system.
- Fulfills the role of Management Representative for the Quality System to FDA and Notified Body including leadership of the Management Review process.
- Manage and oversee all regulatory activities including US regulatory submissions for 510k, IDE's, PMA, international regulatory submission registrations and all other regulatory activities.
- Provides direct leadership of management review, complaint handling, internal audit and CAPA processes. Conducts internal audits to QSR and ISO13485.
- Coordinate quality and regulatory audits both internal and external.
- Ensures Quality and Regulatory training is conducted and effective for company personnel.
- Establishes quality metrics and conducts trend analysis of quality performance. Publishes performance reports.
- Work with other departments to schedule appropriate vendor/supplier audits, assist with implementing, prioritizing and closing audits.
- Maintain the company's 13485:2003 registration

Qualifications:

- Bachelor's Degree in a technical discipline, preferably in a life sciences or mechanical engineering field. Advanced degree is preferred, but not required.
- Medical device knowledge including thorough understanding of FDA Quality System Regulation, ISO 13485, the EU Medical Device Directive (MDD) and other medical device standards is required. Knowledge of other international regulations (Canada, Australia, Korea, and China) is desired.
- 10+ years of experience in a quality management environment within a medical device company.
- Experience with FDA Inspections, Establishment Registration, Listing, 510(k) submissions, ISO Technical file and incident reporting\adverse events (MDR) and recalls required.
- Previous managerial skills required as this position will require management of others.
- Good understanding of standard quality control/ quality assurance methods
- Desire Certified Auditor credentials and Regulatory Affairs Certified (RAC) by RAPS.
- Strong technical writing ability, including appropriate presentation skills.
- Detail-oriented work habits.

 Computer proficiency

Note: This job description is not intended to be an exhaustive list of all duties, responsibilities or qualifications associated with this position.

To apply for this position, please submit a resume to: ltravis@walkmed.net

Englewood, Colorado 80112
www.walkmed.net

Quality Engineer

Sound Technology, Inc., is a leading manufacturer of high-quality medical ultrasound transducers. We are located just south of the Denver Tech Center and are seeking an experienced **Quality Engineer**.

The quality engineer will be responsible for developing and interpreting quality standards, establishing Quality programs for new and existing products, and reporting to management on quality-related issues in a regulated environment. This is a great opportunity to join our Quality team for our Denver manufacturing facility.

Responsibilities for this position include:

- Administering the CAPA System
  - Providing key support during customer audits, interfacing with customer representatives concerning quality issues and assuring that effective corrective action is implemented.
  - Facilitating resolution of complaints, recalls, and customer feedback.
  - Leading internal audit program
  - Serving as primary Quality Assurance resource for problem identification, resolution, and continuous improvement such as required for nonconformance, corrective and preventive action programs.
- Design Control Support
  - Supporting STI's external customers in quality, special projects, and continual improvements efforts.
  - Supporting design and development in design reviews, risk management, reliability, safety, hazard assessment, validation and qualification methods, and design transfers to manufacturing.
  - Developing, applying and maintaining quality requirements and standards for design and development projects.
- Supplier Quality
  - Establishing quality requirements and quality plans for supplier; conducting supplier audits
  - Supporting purchasing in selecting and monitoring suppliers.
  - Providing QA reports on STI's external suppliers. Interface with supplier quality representatives concerning problems with quality assurance and assure that effective corrective action is implemented.
- QA Representative for Change Control
  - Assisting with establishing, implementing, and maintaining the QMS to cGMP requirements
  - Reviewing customer purchase orders, contracts, and change request to ensure that the necessary criteria and provisions are included in the quality and process plans.
  - On site training for QMS procedures. Need to be able to design training program with feedback loops that ensure site understanding on quality standards and activities.
- Product and Manufacturing Support
  - Supporting manufacturing engineering in process control, process validations, process improvement, process training programs, software control and validations, risk management.
  - Developing, applying, and maintaining quality requirements and standards for manufactured products.

- Designing, installing, and evaluating quality processes, sampling systems using statistical techniques, inspection processes, test methodologies, and quality plans. Ability to prepare reports with data showing effectiveness of these systems is critical.
- Serving as the meeting facilitator for the Materials Review Board (MRB).

The ideal candidate will have:

- Minimum of 5 years experience with GMP quality systems, medical device manufacturing and supervisory experience preferred.
- Strong knowledge of quality systems including ISO and FDA, proven success in detailed root cause analysis and corrective actions. Knowledge of international standards a plus.
- Demonstrated attention to detail and problem solving skills. Must be able to work in a participative, team oriented environment.
- Excellent written communication and interpersonal skills along with strong time management and organizational skills
- Excellent computer skills (including, but not limited to: Windows, MS office, ERP systems). JMP statistical software preferred.
- ASQ certification preferred but not required.

We offer a competitive salary, outstanding benefits and a flexible, small-company work environment. In return, we are looking for hard-working, flexible and positive-minded individuals.
To apply for this position, please email a cover letter and resume along with salary history to hrdenver@sti-ultrasound.com.

Sound Technology is an Equal Opportunity Employer
Sound Technology is committed to a drug free workplace

Requisition #: 2178

Excerpt from an e-mail to Boulder Section:

My partner at Black Bear, Jeff Keener, has a complete list of all the available quality jobs and can provide you with all the information needed. I have cc'd him on this email.

Regards, Scott Conner www.blackbearconsultants.com 503-250-3516

Colorado Performance Excellence

Thanks for your interest in the Colorado Performance Excellence (CPEx) organization! We represent a community of organizations and individuals dedicated to performance excellence. Other organizations that have adopted the performance excellence framework have demons-trated: Increased organizational learning and development; A sound management framework; Proven financial results; Documented benefits to employees, customers, the community, and other stakeholders; Ability to use the state award as a stepping stone to the Baldrige National Quality Award, jointly administered by the U.S. Department of Commerce and ASQ Society.

Monfort Sustainable Transformation Program

The Monfort Institute will offer a new half-day leadership workshops based on research on the Malcolm Baldrige National Quality Award recipient organizations. The workshops in the series will be offered at the UNC Center at Centerra in Loveland. For more information or to Register . Please enter the CPEx code when registering. Cont on next page
Workshops include the following:

Executing for sustainable High Performance - January 11, 2011, 8:30 a.m. - 12:30 p.m.

Developing a Learning Culture for High Performance - February 8, 2011, 8:30 a.m. - 12:30 p.m.