



The next ASQ Boulder Section meeting will be held on Thurs, March 24th 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.

MARCH CHAIR MESSAGE

"If an organization provides value to you, either in your professional or personal life, what prevents you from getting involved? According to our winter ASQ Section 1313 survey, 89% of respondents stated that the ASQ National office provides value in your professional work life while only 66% of respondents said that ASQ Section 1313 provides value in your professional work life. Why is this? What value does ASQ Nationals provide over our local section? What can you do to get involved and make a difference?"

Thank you to those of you who attend the meetings on a monthly basis and also to those of you who have supported our section by being a presenter in the past fiscal year. Feedback from our survey indicates that we have done a good job in scheduling topics for the current year and need to focus our topics on basic quality tools such as Cause and Effect analysis and Control Charts, as well as Lean Six Sigma and Quality Systems. As we prepare to plan for our 2011/2012 fiscal year, please consider getting involved either as an officer or as a presenter or both. This is OUR organization.

Our section will hold its officer elections during the May 2011 section meeting. My time as chair person is drawing to a close as the ASQ National rules state that a person cannot serve more than two consecutive years as a local section chair person. To achieve customer satisfaction and continue to improve the customer perception on the value add of ASQ Section 1313 to members' professional work lives, including filling the meeting speaker schedule for next year, your help is needed. Please contact me directly if you would like to be an active part in our organization.

I look forward to seeing you at our next meeting on Thursday, 24th March 2011!

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 ASQ Communications

MAIL: 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 un-tapped due to limited number of student applicants.

ASQ National News

Engineering Resource Announced

In February of this year, the National Academy of Engineering (NAE) announced the official launch of the [Changing the Conversation](#) website. "The site," states a message from the NAE, "is intended to help improve the effectiveness and impact of the engineering community's efforts to communicate to the public about engineering.

"The NAE encourages all interested parties visit the site and share it with friends and colleagues. The site is part of a project funded by the National Science Foundation.

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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: 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: 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 wellsolly@comcast.net	Title: Education Chair Name: John Beachman Phone: 720-313-2746 e-mail: john.beachman@covidien.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: Certification Name: Wells Lange Phone: 303-604-6694 E-mail: wellsolly@comcast.net	Title: Programs Name: Guy Harris Phone: 303-470-7020 E-Mail: harrisgb@comcast.net

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Upcoming ASQ #1313 Tutorial & Main Presenters as of: March 12th, 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**.

March 24th

Main Talk: Byron Murray, topic is: **PCBA Design for Six Sigma Project**

Abstract: A review of how the Six Sigma principals, DMAIC (Define, Measure, Analyze, Improve and Control) can be used for a Printed Circuit Board Assembly design improvement project.

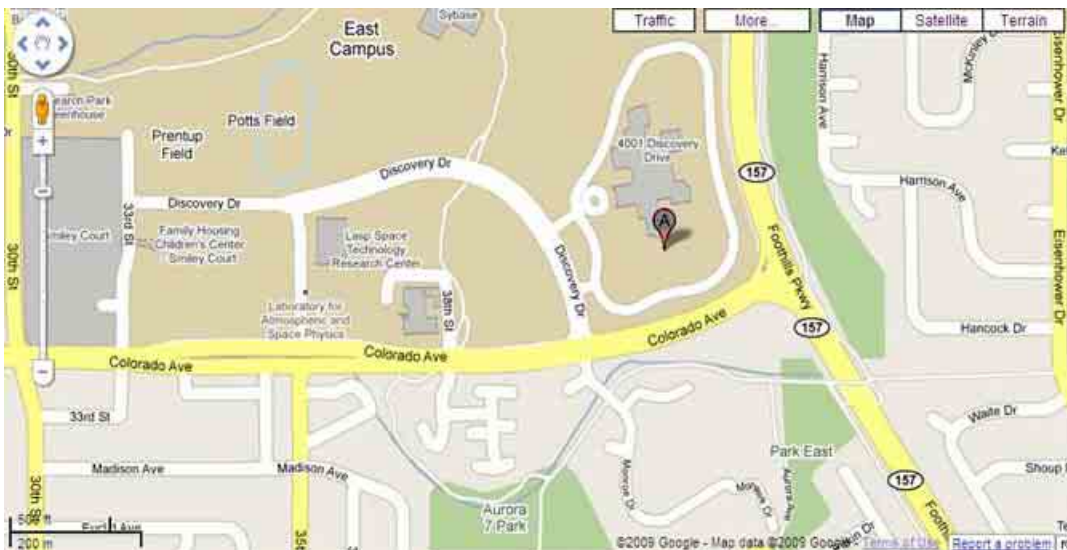
Biography: Byron is a Product, Systems, Quality, Project Professional. He has held business leadership positions at NEON, Advanced Energy, Vaisala, Quantum, Carrier Access, Exabyte and Sanmina. Current job title is Sr. Quality Assurance Coordinator/Engineer. In this position he has responsibility for all quality aspects of a product including systems development, supplier, factory, service and customer quality. A graduate of Colorado State University in Industrial Engineering, He started as a Process Engineer with Customer Engineer responsibilities, solving issues and implementing new products for Sanmina.

He has 18 years of experience with new product introductions, supplier management, and customer service. He gets the right things done for the project or program. He is a team player who is not afraid to step up to the plate or ask for help when needed.

Specialties: AAA Certified Lean Six Sigma Green Belt, 2010 , Agile software design Certified ScrumMaster (CSM), 2009 Agile software design Certified Product Owner (CPO), 2009 ASQ Certified Software Quality Engineer (CSQE), 2007 Production Parts Approval Process (PPAP) Reliability Modeling, Growth and Demonstration Testing (RDT) Failure Reporting and Corrective Action (FRACAS) Design and Process Failure Modes and Effects Analysis (FMEA) ISO 9000, 14000 and Auditing, Asian and US outsourcing

30-Min Tutorial: Rebecca Jessep “ASQ Re-Cert Process”

The March 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 on Wed, 24th of April:

**Combined Meeting of
ASQ Frontrange Sections**

And-

Boulder

Denver



Northern Colorado

ASQ Supports OUR STUDENTS' Education!

Students: Attend on April 20th and receive a \$10 Barnes & Noble gift card to help buy a book!

Learn about quality and organizational performance improvement in the medical device industry.

ASQ Vision

By making quality a global priority, an organizational imperative, and a personal ethic, ASQ becomes the community of choice for everyone who seeks quality technology, concepts, or tools to improve themselves and their world. www.asq.org

MAIN SPEAKER: Francis Kim, VP of Quality, Medtronic Surgical Technologies Bio: Francis has nearly fifteen year career with Medtronic and has held leadership positions in Quality, Research and Development, Engineering and Operations capacities in Corporate QA/RA, Diabetes, and Cardiac Surgery businesses.

Why is Francis presenting to an ASQ meeting? Francis will discuss the Quality function and its importance to the medical device industry.

When and where is it? Wednesday April 20th, 2011 start at 5:45 PM

Jefferson County Public Library – Arvada Branch 7525 West 57th Avenue Arvada, CO 80002

Suggest to [Mapquest it](#). Call 303-235-5275 (for driving directions)

RSVP deadline - Friday, April 15th, 2011 RSVP by email to Joe Wojniak, Boulder Section Vice-Chair, joe.wojniak@covidien.com

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

U.S. Food Safety Bill Passed

ASQ Calls for Third-Party Assessment With Auditing Oversight

U.S. President Barack Obama recently signed the Food Safety Modernization Act into law. 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

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**

65th Annual Quality Improvement Training Conference

The 2011 World Conference on Quality and Improvement May 16th-18th promises to be our best event yet. Internationally recognized [keynote speakers](#) will start the three-day conference, which is filled with 100 training sessions featuring the focus areas of building a quality culture, global, organizational excellence, quality basics, and risk management. Search the [conference program](#) today to select the sessions that are right for you and take a look at what's in store for you this year!

Want to see what you missed last year? ASQ invites you to take a look back at the 2010 World Conference on Quality and Improvement. [Conference highlights](#) showcase past keynote speakers, a conference recap, team award recipients, videos, and photos.

Don't miss another year! [Register today](#) using the tips below to lead you to savings.

Tips to lead you to savings! Check out these savings opportunities to stretch your conference travel budget—without missing out on the premier quality conference of 2011.

Save big when you:

- Become an ASQ member and save \$200 compared to nonmembers.
- Register by April 1, 2011, and save \$100 with the early-bird rate.
- Bring a buddy and save up to \$400 per person with groups of three or more.
- Are a repeat attendee. As a repeat attendee, you'll receive a personal special price invitation from ASQ.

Keynote Speakers



Adm. Thad Allen
USCG (Ret). National
Incident Commander



J.J. Irani
Assistant to the Director of
Research and
Development, Tata Steel



Barbara Corcoran
The Corcoran Group

May 16-18 Pittsburgh, Pa. News Release

ASQ World Conference Focuses On New Role of Quality

Build Your World Conference Schedule at: www.asq.org

ASQ's 2011 World Conference on Quality and Improvement, which will be held May 16–18 in Pittsburgh, Pa., has announced its preliminary program. The program provides information on preconference courses, concurrent sessions, conference events, and keynote speakers. Search the more than 100 sessions to build your perfect schedule.

The New Role of Quality: Tomorrow's Applications of Proven Quality Tools

Today's challenges have brought many to re-examine the role that quality can play in the organizations and communities that we work and live in. In the face of these challenges, some people are getting back to the basics, and others are looking to innovation and creativity to pave the way.

Today, more than ever, quality has a role to play. Whether traditional or new, conservative or inventive, quality is critical.

Join us in Pittsburgh in 2011 to take on the New Role of Quality.

- Learn new and classic quality tools, methodologies, and techniques.
- Network with more than 2,000 attendees and exhibitors.
- Benchmark best practices with the International Team Excellence Award Process.
- ***Gulf Coast oil spill disaster commander among three keynote addresses***
The content of the 2011 ASQ World Conference on Quality and Improvement, May 16-18, 2011, in Pittsburgh, Pa., seeks to re-examine the role that quality can play in the face of today's challenges.

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 3Q 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>.

ASQ BOULDER SECTION #1313 COURSE DESCRIPTIONS *Revised 03-12-2011*

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 720-313-2746 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 03-12-2011

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, workbooks, 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 UPDATES, 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) 720-313-2746, 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).

Customer Experience Management

Denver, Colorado
March 31 - April 1, 2011

The Institute of Integrated Customer Experience Management (IICEM) is a premier training institute. We train organizations in the concepts of customer experience delivery and approaches for enhancing performance.

IICEM is delighted to offer the regularly scheduled Two Star course in Customer Experience Management in Denver. This course covers critical topics relating to customer satisfaction improvement. This course will train you to ask the right questions, analyze the current situation, and how to make improvements that stick.

Learn structured approaches to Customer Experience Management

IICEM trainings assist businesses to deliver satisfying Customer Experiences (B2B and B2C) and has shown to increase the customer satisfaction scores; leading to increased profit margins and significant market share gain!

Drive organization-wide transformation

This training is ideal for individuals and managers tasked with improving customer satisfaction and retention.

Course completion certificates will be provided at the end of the course.

To register please contact Heather at

(719) 799-6457 or (877) 574-6865

heatherjb@iicem.org

Early Bird and Group Discount available

Space is limited



- Go beyond the cliché of customer service
- Learn why customers really stay or leave
- Breakthrough approach to customer retention and market share growth
- Succeed in current economic conditions



<http://www.iicem.org>

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.

ASQ Certification Exams 2011 Schedule

Certification	Application Deadline	Exam Dates
1. CQT - Quality Technician 2. CRE - Reliability Engineer 3. CQI - Quality Inspector 4. CMQ/OE – Manager of Quality & Organizational Excellence 5. CSSBB - Six Sigma Black Belt 6. CHA - HACCP Auditor 7. CBA - Biomedical Auditor 8. CMBB - NEW Master Black Belt	Every January and August August 12, 2011	Every March and October October 1, 2011
9. CQE - Quality Engineer 10. CQA - Quality Auditor 11. CSQE - Software Quality Engineer 12. CQIA – Quality Improvement Associate 13. CCT - Calibration Technician 14. CQPA - Quality Process Analyst 15. CSSGB - Six Sigma Green Belt 16. CPGP - Pharma GMP Professional	Every April and October April 15, 2011 October 14, 2011	Every June and December June 4, 2011 December 3, 2011

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

Colorado Quality Executive Network (CQEN)

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



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



Covidien Job Description

POSITION Sr. Quality Engineer
TITLE:
DEPARTMENT: Quality Assurance
BUSINESS UNIT: Respiratory
REPORTS TO: Quality Engineering Manager

SUMMARY OF POSITION:

Provide quality engineering support in design and development of medical device products, and facilitate the application of design controls.

ESSENTIAL FUNCTIONS:

1. Review new and modified product designs for quality characteristics, including manufacturability, serviceability, testability, reliability, and conformance to product requirements.
2. Ensure that product development projects and changes to existing products are conducted in compliance with the FDA Quality System Regulation.
3. Ensure successful transfer of new products to production facility. Review production processes for quality of validation.
4. Review and approve verification and validation test plans. Ensure verification results demonstrate compliance to medical device standards.
5. Provide training to project teams on verification/validation statistical methods and design controls.
6. Lead product risk assessment efforts within product teams.
7. Review Design History Files and Technical Files for conformance to applicable requirements.
8. Provide Quality support to facilitate the rapid resolution of product complaints and/or safety issues.
9. Conduct internal quality system and supplier quality audits.

DEPARTMENT SPECIFIC/NON-ESSENTIAL FUNCTIONS:

Other duties as assigned with or without accommodation.

MINIMUM REQUIREMENTS:

<i>Education:</i>	BS or MS in an engineering discipline
<i>Experience:</i>	5+ years of quality engineering experience
<i>Skills/Competencies:</i>	Working knowledge of and auditing experience to the FDA Quality System Regulation, ISO 13485, and the Medical Device Directive. Experience with test methods and standards for the design, verification, and validation of medical device products. Skilled in test plan development and root cause failure analysis. Skilled in statistical methods, including ANOVA, statistical process control, sampling plans, gauge R&R, and design of experiments. Good verbal (including presentation) and written communication skills, especially technical report writing. Ability to effectively work on project teams.
<i>Preferred Skills/Qualifications:</i>	Familiar with reliability analysis and test methods. Familiar with ISO 14971. Experience in risk evaluation techniques, such as FMEA, fault tree analysis or HACCP. Manufacturing engineering or manufacturing quality engineering experience preferred. ASQ CQE or CRE certification.
<i>Other Skills:</i>	Spanish proficiency desirable

ORGANIZATIONAL RELATIONSHIPS/SCOPE:

Will be working in cross-functional teams as the Quality System expert.

WORKING CONDITIONS:

Normal office conditions. Up to 10% travel required.

DISCLAIMER:

The above statements are intended to describe the general nature and level of work being performed by employees assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of employees assigned to this position.



Call for 2011 Examiners

-Registration

Info on Next Page

2011 Examiner Registration Is Open

The 2011 examination season looks like another year of great opportunity for CPEX. We have new and returning applicants at all levels and sectors that are currently preparing to benefit from the feedback provided by our examination teams.

If you have ever thought about being an examiner, now is the time. Join with our returning examiners to have an experience that is "truly meaningful - educationally, professionally and personally." (2010 Examiner) Visit our [Becoming an Examiner](#) page to learn about the pros and cons of the examiner experience and then complete our New Examiner Registration form: [New Examiner Registration](#).

New Examiner Class options:

March 29 at Avista Adventist Hospital in Louisville,
March 31 at Colorado Technical University in Colorado Springs,
April 5 at the Monfort Campus in Loveland, or
April 7 at The Aurora Medical Center in Aurora

All Examiner Class options:

May 12, Regis University, Main Campus, Denver
May 16, Regis University, Main Campus, Denver

If you are a previous examiner, we hope you are rested and ready for the new assessment and feedback cycle for 2011. We need your experience and skill back on the CPEX Board of Examiners. Please complete the [Returning Examiner Registration](#) form for the All Examiner classes on May 12 or May 16 at the Regis Main campus in Denver. You'll receive information on this year's Case Study in early April. Examiner fees are waived if you bring a new examiner from a non-applicant organization with you. We are expecting 20 applicants this year, and we need your return, plus assistance in recruiting new folks.

Please contact Jim Walker at drjimw@hotmail.com or Tom Mauro at tmmauro@aol.com or call 303-893-2739 if you have any questions about New or All Examiner training for 2011. We look forward to your participation.

ABOUT CPEX

Colorado Performance Excellence's vision is to create a culture of excellence that is pervasive throughout Colorado and the Rocky Mountain Region including Montana and Wyoming. It serves the people of the region by using a proven program of innovation and continuous improvement that generates outstanding results. CPEX fulfills this promise through training and education, assessment and feedback, recognition and awards, networking, and the sharing of best practices. Visit CPEX at www.coloradoexcellence.org. CPEX is now operating as Rocky Mountain Performance Excellence for Montana and Wyoming at www.rmpex.org or at the CPEX website.

ABOUT THE BALDRIGE NATIONAL QUALITY AWARD

The award was established during the Reagan administration in 1988 and continued by all other administrations since then. The criteria used to determine award recipients at the various levels are based on the Baldrige criteria, which any organization can use to improve overall performance. Seven categories make up the award criteria: Leadership; Strategic Planning; Customer and Market Focus; Measurement, Analysis, and Knowledge Management; Workforce Focus; Process Management; and Organizational Results.

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