



**Next ASQ Boulder Section meeting will be Thurs, Feb 25<sup>th</sup> at the Quantum Corp facility in Boulder. Tutorial starts at 5:30pm and the main presentation starts at approx 6:20pm. Please see page 3 for more location and meeting details.**

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**FEBRUARY CHAIR MESSAGE**

Are you interested in quality tools and alternate energy in Colorado? In line with our new mission statement, "to promote the quality profession through personal development of members in order to enhance the profitability of business in Boulder and the surrounding geographical communities", we are proud to host Gary Vansuch from NREL speaking on "Applying Quality to Research and Development: Helping NREL Succeed and Thrive" as the main speaker for our February 25th, 2010 meeting to be held again at Quantum Corporation, Boulder. This talk will focus on the role of quality tools in R&D. You don't want to miss this talk from Gary!

Our January meeting presentation by Guy Harris, on "Business Strategies Board Game", facilitated interactive discussions on best methods as responses to potential real life situations that quality professionals may encounter. It was exciting to welcome a few new attendees to our meeting. I challenge each of you reading this to invite and/or bring at least one person to the meeting with you in February. We are still offering new ASQ member candidates \$50 towards the cost an annual society membership fee.

One of the critical functions of our section, in addition to providing value added monthly meeting topics, is ASQ certification review courses. At this time, the Section 1313 Education Chair position is open. This is a prime opportunity for increasing your professional network, engaging in the success of the section, and to earn 1.5 RUs for each year of service. Please see me at the February meeting for full details and to sign up for this opportunity for the remainder of the 2010 fiscal year (serving until the end of June 2010).

Would you like to be more involved in the success of our organization for next year? Officer elections for next year are going to be held in April 2010. I do greatly appreciate the support of each of the current elected officers and committee members who make our section a success. Thank you for your time that you give to ASQ.

"Networking on LinkedIn". We have a new Section #1313 LinkedIn page (titled: [American Society for Quality \(ASQ\) Section 1313 - Boulder, Colorado](#))  
Sincerely,  
Rebecca Jessep  
ASQ Section 1313 Chair

**ASQ'S Customer and Member Center:**

**E-MAIL:** [help@asq.org](mailto: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 website at: [www.asq.org](http://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](http://www.asq1313.org)

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

**ASQ National News**

**Read the Latest ASQ White Paper on Innovation and Quality**

Learn how highly profitable companies are using unique approaches to strike a balance between efficiency and innovation by reading the latest ASQ white paper, "Fresh Thinking on Innovation and Quality." In the report, ASQ profiles two major companies, DuPont and Procter & Gamble, well-known industry innovators that have taken steps to fully integrate the creativity-generating functions of R&D and product development with regular process management structures and practices. For more information on this, see the ASQ main website at: [www.asq.org](http://www.asq.org)

ASQ National News is continued on page 4

## ASQ#1313 Officers & Committee Chairs 2009-10

ASQ Section 1313	Boulder, CO
<b>Title: Chair</b> Name: Rebecca Jessep Phone: 303-587-7067 E-mail : <a href="mailto:rebeccaessep@hotmail.com">rebeccaessep@hotmail.com</a>	<b>Title: Vice Chair</b> Name: Joe Wojniak Phone: 800-635-5267 E-Mail: <a href="mailto:joe.wojniak@yahoo.com">joe.wojniak@yahoo.com</a>
<b>Title: Secretary</b> Name: Melinda Schones Phone : 303-359-5531 E-mail: <a href="mailto:mschones2002@yahoo.com">mschones2002@yahoo.com</a>	<b>Title: Treasurer</b> Name: Ewald Schelert Phone: 303-702-9009 E-mail: <a href="mailto:Schelert@mesanetworks.net">Schelert@mesanetworks.net</a>
<b>Title: Re-Cert</b> Name: Larry Derouin Phone: 303-431-9287 E-Mail: <a href="mailto:LWDerouin@comcast.net">LWDerouin@comcast.net</a>	<b>Title: Internet &amp; Website</b> Name: Arnold Miller Phone: 303-466-2631 E-Mail: <a href="mailto:arn_miller@earthlink.net">arn_miller@earthlink.net</a>
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### MBNQA

For info on the Malcolm Baldrige National Quality Award Program, visit [www.quality.nist.gov](http://www.quality.nist.gov)

### CPEX

For info on the Colorado Performance Excellence Program (Colorado State quality and business performance program), visit [www.coloradoexcellence.org](http://www.coloradoexcellence.org) Local contact: Executive Director, Mr. Tom Mauro [tmmauro@coloradoexcellence.org](mailto:tmmauro@coloradoexcellence.org) (or) at 303-893-2739 Please see **page 11** in this newsletter for the most recent information on upcoming winter 2009 CPEX activities and events. **The Boulder ASQ Section is a sponsor of the CPEX at the Elk Level / Level 1.**

**ASQ #1313 Tutorial & Main-Presenters for Upcoming Meetings** as of: **Feb 14<sup>th</sup>, 2010**

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**.

Feb 25<sup>th</sup> Gary Vansuch of the National Renewable Energy Lab (NREL) in Golden, CO on: **“Applying Quality to Research and Development: Helping NREL Succeed and Thrive”**

**30-Min Tutorial:** Rebecca Jessep, Covidien Corp / Boulder and Section Chair on **“ASQ Recertification”**

The February ASQ meeting will be at Quantum Corp / Boulder Research Park facility  
4001 Discovery Drive, Suite 1100 Boulder, CO 80303 (“the A” just below)

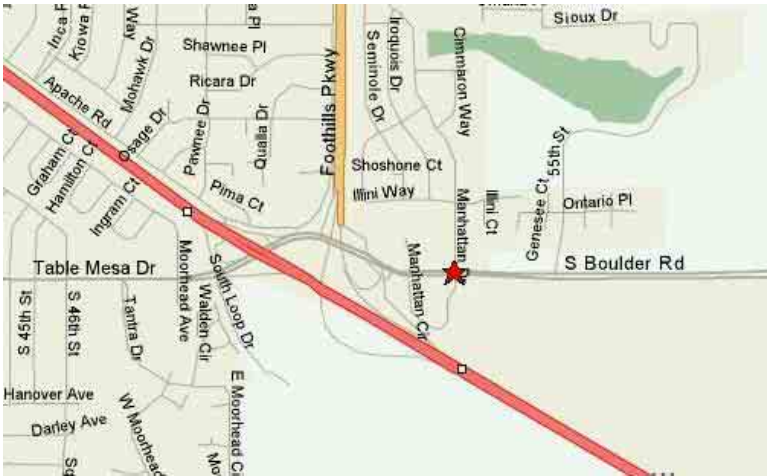


ASQ Meeting attendees should park on the North side and enter through the main building doors on the North-East side. (Note: These are not the Quantum doors but doors to the main building. If any problems, use: 303-587-7067 as the contact for the meeting.

March 25<sup>th</sup> Ron Sedlock of quality Catalyst Inc. on: “Quality of Service Operations”.

**30-Min Tutorial:** Topic is: “Practical Aspects of Networking” by the session attendees

The meeting place will be at Day-Inn Hotel located at 5397 S. Boulder Rd 80303 (see map below).



## [ASQ National News , cont](#)

### **ASQ Responding to Auto Recalls**

With the recent Toyota recalls, the topics of lean manufacturing and quality are getting a lot of press. ASQ is proactively responding to those stories, developing a webinar about the quality aspect of the recalls, and answering media inquiries on the issues. Ron Atkinson, ASQ past president and recently retired 35-year veteran of the auto industry, talked with a reporter from the *Milwaukee Journal Sentinel* about quality and auto recalls. The ASQ main website at: [www.asq.org](http://www.asq.org)

### **Refer Someone to ASQ in March and Win BIG!**

For every member you recruit in March through the Each One Reach One (EORO) recruitment program, you'll earn ASQ Bucks (1 ASQ Buck = \$1) and be entered to win special prizes such as: all expenses paid trip to the World Conference on Quality and Improvement (\$2,000 value); one free registration to the World Conference (\$900 value); or a Dell Mini 10v Netbook (\$250 value). For more information, go to the [www.asq.org](http://www.asq.org)

### **ASQ 2010 Manufacturing Outlook Survey Shows Some Recovery**

*Data Shows Respondents Also Expect Continued Cost-Cutting Measures*

**Milwaukee, Wis.** — A new ASQ (American Society for Quality) survey shows a majority of manufacturers are optimistic about a small economic uptick in 2010 at their organizations. However, respondents believe further cost-cutting measures will continue to be implemented. The results show a majority of respondents (64.7%) employed in the manufacturing sector predict their organizations will experience some financial recovery in 2010. More than 1000 manufacturing professionals around the world responded to the online survey from December 2-13.

Other events that respondents predict their organizations will experience in 2010:

61.3% believe their organization will create processes to reduce costs

44.8% expect a pay freeze

41.4% predict a hiring freeze at their organizations

35.2% will have mandatory budget cuts

27.8% expect staff layoffs

24.7% anticipate reduced employee benefits

Respondents were also asked what one tip they would give to manufacturers to ensure revenue growth in 2010. The top four tips from respondents were:

Continue to take part in continuous improvement practices and increase use of quality processes

Increase customer satisfaction

Implement more lean processes  
Reduce costs

“Since the manufacturing sector greatly impacts the economic climate, this survey may serve as a good predictor of the overall 2010 financial outlook,” said ASQ President Peter Andres. “This information will also help ASQ keep a good pulse on the right tools and resources to better serve the needs of our members and customers in the new year.”

## [ASQ Online Community Offers New Functionality](#)

Ever want to upload and share files, post comments, and instant message with quality professionals who share your interests? Now you can with the announcement of ASQ's newly launched online community. The community site is completely user driven, allowing you to easily create (or join) a network or blog on a particular topic. Visit this new ASQ services site at: <http://community.asq.org>

## [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.



## [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!

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- Manage your processes effectively
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**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](http://www.asq.org/iso9001) today.

## [ASQ Boulder Section News](#)

## USPS correspondence address for the Boulder ASQ Section is:

**ASQ Boulder Section**

**P.O. Box 21595**

**Boulder, CO 80308-4595**

Note: All education & course registration materials should be sent to Section Education Chair (see page 10)

## Boulder Section's Charity Donation Program:

In 2008, the Boulder Section exec board in approved a policy of donating to bonafide local charities of \$100 per calendar quarter. If you have a bonafide local charity in mind, let a Section officer know about it at a 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 with you any information regarding your charity to pass on to, and for review by the exec board at their next meeting. Suggestions for the 3Q and 4Q of 2010 are being accepted.

## 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.asgquality.org>.

**The following article is from Joe Wojniak of Covidien/Boulder Corp and Boulder Section Vice-Chair**

## Audits and being Audited

By Joe Wojniak, ASQ CQE, Covidien

A 4 day audit wrapped up at the Covidien Watertown facility from Covidien Regulatory Affairs. Auditing is a difficult process for both the auditee and the auditor. The auditee because personal work is being reviewed throughout the facility with the benefit of hind sight (which is always 20/20 they say) and for the auditor because they are essentially giving "corrective" feedback i.e. negative feedback with the purpose of correcting perceived shortcomings in the quality management system.

The emphasis of the corporate auditors was to simulate an FDA Inspection with a few modifications, such as being willing to modify the schedule in order to be as unobtrusive as possible to the daily operations. 21 CFR Part 820 was the standard being audited to. Here's what I observed of the auditor's strategies: The audit team comprised of 2 auditors, each reviewing different sections of the QMS. Information about the facility was requested about 2 months before the audit date. 1 month was given to complete the requested information. The information was comprehensive of the quality system and of the facility and products being manufactured.

From this information the audit agenda was developed and shared about 1 week before the audit date. The auditors for the most part worked independently of each other, asking only clarifying questions of each other from time to time. I've noticed that some auditors are satisfied with relatively small sample sizes to determine compliance to procedures. In this case, random and stratified samples were taken of the past 2 years. Samples were chosen from the facility's higher volume products, also using information from customer complaints and the CA/PA system to choose particular areas to sample from. Relatively large samples were used and this definitely made the audit very comprehensive.

The auditors asked specifically to observe the operations of particular product lines, reviewing demonstrated practice vs. work instructions. As an auditee, our strategies were as follows:

1. Provide the information requested and only the information requested, in a timely manner.

2. Stay on schedule (not faster or slower).
3. Have subject matter experts answer auditor questions directly when appropriate.

The audit room team was supplemented by a support team that retrieved and reviewed requested documents, located and briefed subject matter experts as needed. Efforts were made to limit conversations pertaining to operations within the audit room itself, such discussions happened off-line with the support team and the Quality Manager.

The audit itself is seen as a microcosm of the way production is conducted. Being prepared, having cross functional support, and involving those responsible for the areas being audited were key to being successful. To learn more about auditing visit: <http://www.asq.org/qualityprogress/index.html>

## **ASQ BOULDER SECTION #1313 COURSE DESCRIPTIONS**

Revised 02-08-2010

### **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, 5<sup>th</sup> 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 Boulder Section Education Chair, Gretchen Stewart at: [stewartgm@qwestoffice.net](mailto:stewartgm@qwestoffice.net) or 303-641-1335

### **1302 – CERTIFIED QUALITY AUDITOR (CQA) REVIEW**

This is a refresher course for those preparing to take the ASQ Certification exam. This course adds strength and credibility to your auditing experience plus prepares you for taking the ASQ Certification exam. The exam requires that you have some auditing background and you need to meet certain minimum requirements. Each student needs to purchase the latest edition of the CQA Primer published by the Quality Council of Indiana (QCI) prior to the first class (cost is approximately \$65). To order, contact QCI at 1-800-660-4215 or [www.qualitycouncil.com](http://www.qualitycouncil.com). A recommended book to also purchase is Management Audits, 3<sup>rd</sup> ed. by Allan Sayle, which can also be purchased through QCI at a discount. It may also be found used, for less on the Internet.

### **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](http://www.qualitycouncil.com). For additional details or questions, contact Education Chair.

### **1321 – SIX SIGMA SIMPLIFIED**

This is an introductory course that will cover the benefits, basic tools, core analysis processes, and success planning for starting a six sigma program. It covers the fundamental concepts for a small to medium size team program and explains the tools for transitioning into a Six Sigma organization. The class has simplified practical applications of improvement processes and data analysis. Course books and other supporting materials are approximately \$27 and are in addition to the course fee. This course is geared toward company leaders of continuous improvement as well as six sigma team members. No prior knowledge of six sigma is required. This is a wonderful class to start the "ideas flowing" for your organizational improvement goals. For additional details or questions, contact the Education Chair.

## **Spring 2010 ASQ Boulder Section #1313 Course Offerings**

Updated 02-18-2010

Course Name	Instructor	Course Fee (1)	Exam Date	ASQ Exam Application Deadline	Course Dates & Times	Course Registration Deadline
<b>spring 2010</b> #1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631 <a href="mailto:arn_miller@earthlink.net">arn_miller@earthlink.net</a> Location: TBD Boulder/Longmont/Broomfield Area	\$400/ \$450	Jun 5, 2010	Apr 16, 2010	Wed Nights 6:00pm-9:00pm Apr 7, 14, 21, 28; May 5, 12, 16; 26 (24 hours)	Mar 31, 2010

Course Name	Instructor	Course Fee (1)	Exam Date	ASQ Exam Application Deadline	Course Dates & Times	Course Registration Deadline

(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, **Gretchen Stewart**, (contact information below) for details.

MORE INFORMATION: Summary from Section web page: <http://www.asq1313.org/courses.html>

#### **FUTURE COURSES & LOCATIONS:**

Contact the ASQ Boulder Education Chair, Gretchen Stewart at: [stewartgm@gwestoffice.net](mailto:stewartgm@gwestoffice.net) or at: 303-641-1335 to see if the class you want can be made available in the Colorado Springs, Denver or Ft. Collins area. Let us know 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>

**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, Gretchen Stewart at: [stewartgm@gwestoffice.net](mailto:stewartgm@gwestoffice.net) or 303-641-1335 to see if the class you want can be made available in the Colorado Springs, Denver, Loveland or Ft. Collins area.

**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).

## **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 #: \_\_\_\_\_

Title: \_\_\_\_\_

Company name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Daytime phone: \_\_\_\_\_ Night time phone: \_\_\_\_\_

FAX: \_\_\_\_\_ or E-mail: \_\_\_\_\_

Course # and Name: \_\_\_\_\_

Course Start Date: \_\_\_\_\_

Course Fee: \$ \_\_\_\_\_ (ASQ Member)      \$ \_\_\_\_\_ (Non-member)

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Please enclose a check payable to "ASQ Boulder Section" and please contact the Boulder Section Education Chair, Gretchen Stewart at: [stewartgm@qwestoffice.net](mailto:stewartgm@qwestoffice.net) or 303-641-1335 for the USPS mailing information from her, for correspondence directly to her.

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

#### **From: The quality Catalyst, Inc.**

Happy 2010 ! Now that the holidays are over and the New Year has begun, it is time to think about upgrading your professional credentials. Hopefully you survived the recent economic downturn but one way to recession-proof your career is ASQ Certification. Employers want ASQ Certified Professionals. Surveys confirm that an ASQ Certified employee makes a higher salary than a non-certified person.

There is nothing wrong with Six Sigma. This basic improvement technique can be traced back to the 1940's (*remember VA/VE?*). What's wrong is that we have gone from a manufacturing economy to a service economy. Even if we manufacture a product we also provide services, both externally and internally. Traditional manufacturing improvement techniques do not always work on services. Service improvement is where quality is heading.

I am offering a one-day class on **How to Provide a Quality Service**. Service quality is not addressed in most quality programs. This is a mistake. Most of us do not make product directly, but all of us do provide a service. There is big difference between product quality and service quality. Understanding this difference is the key. More information on two courses are below. Let me know if you have an interest. I do offer discounts for multiple attendees from the same organization. Like all my classes this class can be brought in-house for additional savings.

I will be conducting a one-day class on January 26 on **How to Prepare to Pass Any ASQ Exam**. I do offer review classes on specific exams based on demand. This class is for those who prefer to study on their own or want to be properly prepared for a review class so that it is really a review.

Below is a course description with some details. If you have any questions, do not hesitate to contact me. I do this class internally for several companies so that could be another option. Also let me know if you have any other quality training needs.

Thanks and have a great year.

2. A one-day class on **How to Provide a Quality Service**. Service quality is not addressed in most quality programs. This is a mistake. Most of us do not make product directly, but all of us do provide a service. There is big difference between product quality and service quality. Understanding this difference is the key to any quality system.

**Course:** How to Prepare to Pass Any ASQ Exam

**Description:** This course explains the process of getting ASQ certified for any of the various certifications offered. You will learn which certification is right for you. You will learn how to do a self-assessment based on the body of knowledge. Body of knowledge common to all certification will be covered. You will learn the best resources and materials to obtain. You will develop a personal study plan. A practice exam is part of this course. Also test-taking strategies will be discussed.

Note: Recommend you take this course about 6 months before you take any exam.

**Date:** January 26, 2010      **Location:** Golden, CO      **Cost:** \$395

**Course:** How to Provide a Quality Service

**Description:** In this course you will learn the differences between product quality and service quality. Each of us provides a service toward our organization. Research has revealed 5 attributes customers want from a service. Learn how you personally can use these attributes to improve your work as an individual and as a team member. The concept of a service recovery will be presented to assure customer satisfaction. Each attendee will create a personal development plan toward becoming an excellent service provider.

**Date:** February 2, 2010      **Location:** Golden, CO      **Cost:** \$395  
Ron Sedlock

phone: 303-716-5873 or 303-587-9153 (cell)

[www.thequalitycatalyst.com](http://www.thequalitycatalyst.com)

## QA Job Posting

### **LABS, Inc.**

#### **Director of Regulatory Affairs & Quality Assurance**

Seeking an experienced candidate to lead our Regulatory and Quality department and direct future direction and growth. Ideal candidate will have high level management experience; will be comfortable managing a small team and equally comfortable working with the Executive Leadership team.

Under administrative direction, assists company with the development, implementation, management and continual improvement of an effective quality assurance program. Serve as a regulatory resource to the organization by providing input and opinions that are in compliance with applicable rules and regulations. Manage and drive systems to closure that are already established with the quality program. Serve as a role model for company values and culture, consultant for internal/external customers on compliance and regulatory issues.

#### **Requirements:**

- Experience working in a highly regulated industry (laboratory, devices, pharmaceutical, or biology)
- Experience in a CAP, ASHI and/or AABB certified laboratory and/or in a GMP or GLP environment
- Knowledge of laboratory services
- Knowledge and experience with regulatory/accreditation agencies
- Knowledge and experience in training and education
- Excellent written communication skills including writing, editing and proof reading.
- Excellent oral communication and facilitation skills.

To apply for this position please send current resume to the following e-mail address:

[resumes@labs-inc.org](mailto:resumes@labs-inc.org).

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## QA Job Posting



[Synchroness, Inc.](#) is seeking a local, Mid-Level **QUALITY ENGINEER** for its Sustaining Engineering team.

We are looking for self-motivated and inquisitive **quality engineers** that enjoy variety and challenges in the workplace. The chosen candidate for this position will have:

- Bachelor's and/or Master's degree in **Electrical Engineering**
- Recent work history in the field of medical device development
- **Familiarity with IEC60601-1** and ECG / Diagnostic ECG device standards
- Familiarity with FDA, Canadian and European device submissions
- Strong skills in technical writing and root-cause analysis
- Demonstrated knowledge of electronic component manufacturers
- Six to ten years industry experience (new graduates will **not** be considered)
- ASQ certification as a Quality Engineer is a plus.

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Our hiring process is technical in nature and begins with a phone screen, followed by a technical on-site interview.

Synchroness is **not** offering relocation compensation for this position. Compensation will range from \$50k to \$70k depending on experience and fit for the position.

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This engineer will be part of a 12-member team that provides ongoing product support for *seven* different medical product lines, each related to cardiac care and therapy. This team is responsible for:

- New feature additions
- Product bug fixes
- Customer problem resolution
- Software verification and validation
- Production releases of design updates

Primary responsibilities of this new team member will include:

- Developing working expertise on all supported products
- Resolving component availability issues
- Troubleshooting and debug of electrical issues
- Response to support requests from field reports
- New component validation planning, execution, and reporting
- Coordination of change notifications with safety agencies and Notified Bodies
- Support of and/or leadership of product re-submissions

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## Colorado CPEX News – Upcoming Events



**Volume 7, Issue 1  
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**Happy New Year from Colorado Performance Excellence! -- Your results are in our name.**

**We hope you have a Sustainable New Year! In 2010 CPEX will be celebrating its 10th anniversary since being founded in April, 2000! Be a part of it!**

### **CPEX Assessment and Feedback Process for 2010**

**Foothills, Timberline, and Peak Application letters of intent are due April 5, 2010 to CPEX headquarters in electronic form. The applications in electronic form are due May 24, 2010. High Plains applications are accepted anytime. Please read the material for applicants online at the Applicants dropdown at [www.coloradoexcellence.org](http://www.coloradoexcellence.org) . Contact Tom Mauro at 303-893-2739 or at [tmmauro@coloradoexcellence.org](mailto:tmmauro@coloradoexcellence.org) for any further information.**

### **CPEX Education for 2010**

**To begin or continue your organization's journey for continuous improvement, please register for some of the CPEX training to be offered throughout Colorado over the next few months. CPEX highly recommends holding this training at your site if you have 5 or more attendees. In this way COO and**

**Dean of Education Jim Walker can customize the training for your organization.**

**All courses are held at the CPEX World Headquarters at 4140 Jackson Street in Denver, CO 80216, unless otherwise noted. Costs for the Intro Workshop are \$150 for the first person from an organization and \$125 for additional registrants from the same organization. Courses at your site are \$100 per person plus travel, lodging, and meal expenses for the instructor.**

**Here is the scheduled public training sessions. For a complete description, please check [www.coloradoexcellence.org](http://www.coloradoexcellence.org) .**

### **High Plains/Introductory Awareness Workshops**

**For folks who want an introduction to the basics of CPEX/Baldrige we have Intro Awareness Workshops scheduled on the following:**

**January 13, 2010**

**February 3, 2010**

**March 3, 2010**

### **Register now**

#### **Application Writing Workshops**

**CPEX is designing Application Writing Classes this year that are level specific. We highly recommend if you have not attended an Application Writing class in the last year that you do so this year. There are significant changes to Category 3 in 2009-10. In particular we have designated these dates for the training.**

**January 21, 2010**

**February 10, 2010**

**March 10, 2010**

**Register now**

### **Examiner Training**

Don't forget Examiner Training this year. If you are an applicant organization you receive two complimentary registrations to examiner training, and we ask you to provide at least two examiners. We may have 15-20 applicants in 2010 so we need 100 examiners plus it's a great way to learn the process from the inside out. In addition the initial training this year will be only 2 days for new examiners and 1 day for returning examiners. The case study process has been streamlined and all work is done online using Examiner Software.

There will be another day of training after independent review and before the site visits for for consensus and site visit training. New Examiner Training will be held at different locations around the state. Regular examiner training will be held at the Regis central campus in Denver.

#### **New Examiner Training**

**March 30, 2010 at Pulte Mortgage LLC in Englewood**

**April 1, 2010 at CPEX headquarters in Denver**

**April 6, 2010 at Poudre Valley Hospital in Ft. Collins**

**April 8, 2010 at Colorado Technical University in Colorado Springs**

### **Register Now**

#### **Regular Examiner Training**

**May 13, 2010 at Regis Central Campus in Denver**

**May 20, 2010 at Regis Central Campus in Denver**

**Register Now**

**If these dates do not work for you, please let me know and we can do specific training at your site for 5 or more folks. The costs for examiner training this year are \$245 for nonprofit new examiners and \$295 for those from for profit organizations. Returning examiners pay \$60. You can register for the classes at the CPEX website [www.coloradoexcellence.org](http://www.coloradoexcellence.org) and pay by credit card or CPEX can invoice you. We are happy to do combined classes on the western slope or in any other location if that makes sense.**

**tmmauro@coloradoexcellence.org or <http://www.coloradoexcellence.org>**