

Volume 20, Issue 6

April 2014

APRIL CHAIR MESSAGE

The ASQ Section survey this year provided feedback that many people would like to see examples of the basic Quality tools and learn how they are applied. This month's meeting will focus on case studies. The basic quality tools have a common theme: counting stuff.

You can count defects, number of cups of coffee served, anything of interest. If you are not sure where to start, think about what the end objective is. This defines the future state. The current state is how things are now. Look for the differences between how things are now and how you'd like them to be. This is the Planning part of Plan-Do-Check-Act. You see what's coming next!

Do! Try some changes out; these can be small steps at first. I am continually surprised at how hard accepting change can be! And I'm including myself in that statement. Since any change, even an improvement, is disrupting the equilibrium of the process there may be a temporary decline in the performance measure. So it's important not to introduce too many changes all at once, unless this is done in a manner where all the different effects can be sorted out. It's also important to implement the change long enough to evaluate the effect. Which brings us to the next step — Check.

Check the effectiveness of the Do step. Can you detect a shift towards the future state? How much of an improvement was needed? (Remember the Planning step? Part of planning needs to be defining how much of an improvement is needed in the near term). Now the hard part, you're probably not done yet.

The next step is Act. Quite often there are unexpected consequences to the actions we take. A common refinement in the Act step is to lessen or avoid the unexpected consequences of the change(s) made.

What's next? Step back from the immediate goal and re-evaluate the situation. Now that this one area is performing better, is there another area that needs improvement? Do we need to continue to focus in the area where we started? Here is a link to the 7 Basic Quality Tools. Each one has a template and a description for how it's used.

<http://asq.org/learn-about-quality/seven-basic-quality-tools/overview/overview.html>

I'd like to hear from you- how are you making the world work better?

Best Regards,

Joe Wojniak, ASQ CQE Boulder Section 1313 Chair

ASQ's Members and Customer Service Center:

E-MAIL: help@asq.org

PHONE: 800-248-1946

FAX: 414-272-1734

USPS ASQ Communications

MAIL: 600 N. Plankinton Ave.

P.O. Box 3005

Milwaukee, WI 53201-3005

We suggest that you go to the ASQ National website 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: <http://asqBoulder.org>

ASQ National News

Emerging Quality Leader Program Site Now Available

Registration for the inaugural class of the ASQ Emerging Quality Leaders Program (EQLP) is now available through the EQLP website, www.emergingqualityleaders.org. If you or someone you know is interested in unique networking opportunities, visiting Fortune 500 companies, or obtaining a top-quality executive mentor, take advantage of this exciting opportunity! Applications are being accepted for the 2014 class.

News continued on page 5

ASQ #1313 Officers & Committee Chairs 2014

ASQ Section 1313		Boulder, CO	
Title: Chair Name: Joe Wojniak Phone: 303-530-6581 Joe.wojniak@gmail.com	Title: Vice Chair Name: -Position Open- Phone:	Title: Secretary Name: Mark Soderberg Phone : 303-905-8157 markosoderberg@hotmail.com	Title: Treasurer Name: John Beachman Phone: 720-313-2746 john.beachman@covidien.com
Title: Re-Cert Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Internet & Website Name: Arnold Miller Phone: 303-466-2631 arn_miller@earthlink.net	Title: Publicity and VOC Name: Byron Murray byron.murray@yahoo.com	Title: SMP Name: Mark Soderberg Phone: 303-905-8157 markosoderberg@hotmail.com
Title: Financial Auditing Name: Ewald Schelert Phone: 303-702-9009 schelert@mesanetworks.net	Title: Education Chair Name: John Beachman Phone: 720-313-2746 john.beachman@covidien.com	Title: Newsletter Co-Editor Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Newsletter Co-Editor Name: Bill Dunford Phone 720-340-0454 billdunford@hotmail.com
Title: Certification Name: Nixon Mead Phone: 720-320-6395 nixonmead@q.com	Title: Programs Name: Dan Clark Phone: 720-326-8240 dpclark@live.com		

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Online Content Exclusively for Members:

ASQ Member Gift
 Celebrate the 25th anniversary of ISO 9000 with this exclusive bundle of resources. This bundle includes:

- Introduction to the ISO 9000 Standards Webcast
- Example Quality Manual
- New ASQ Ask the Experts Blog
- Bonus: ISO 9001:2008 Explained Webinar

Download your gift today!

Advertise in the ASQ Boulder Section e-newsletter in 2014-15!
Effectively get your company's information out in front of Boulder, Broomfield and Denver County QA Professionals.

Rates are.....

\$20 for a 1/4 page one issue (and) \$30 for a 1/2 page for one issue

\$60 for a 1/4 page for all eight issues in a year from the start

(and)

\$80 for a 1/2 page for all eight issues in a year from the start

Contact Gerry Naugle at: gnaugle@earthlink.net (or) 303-591-2830

Upcoming ASQ Boulder Section Meeting

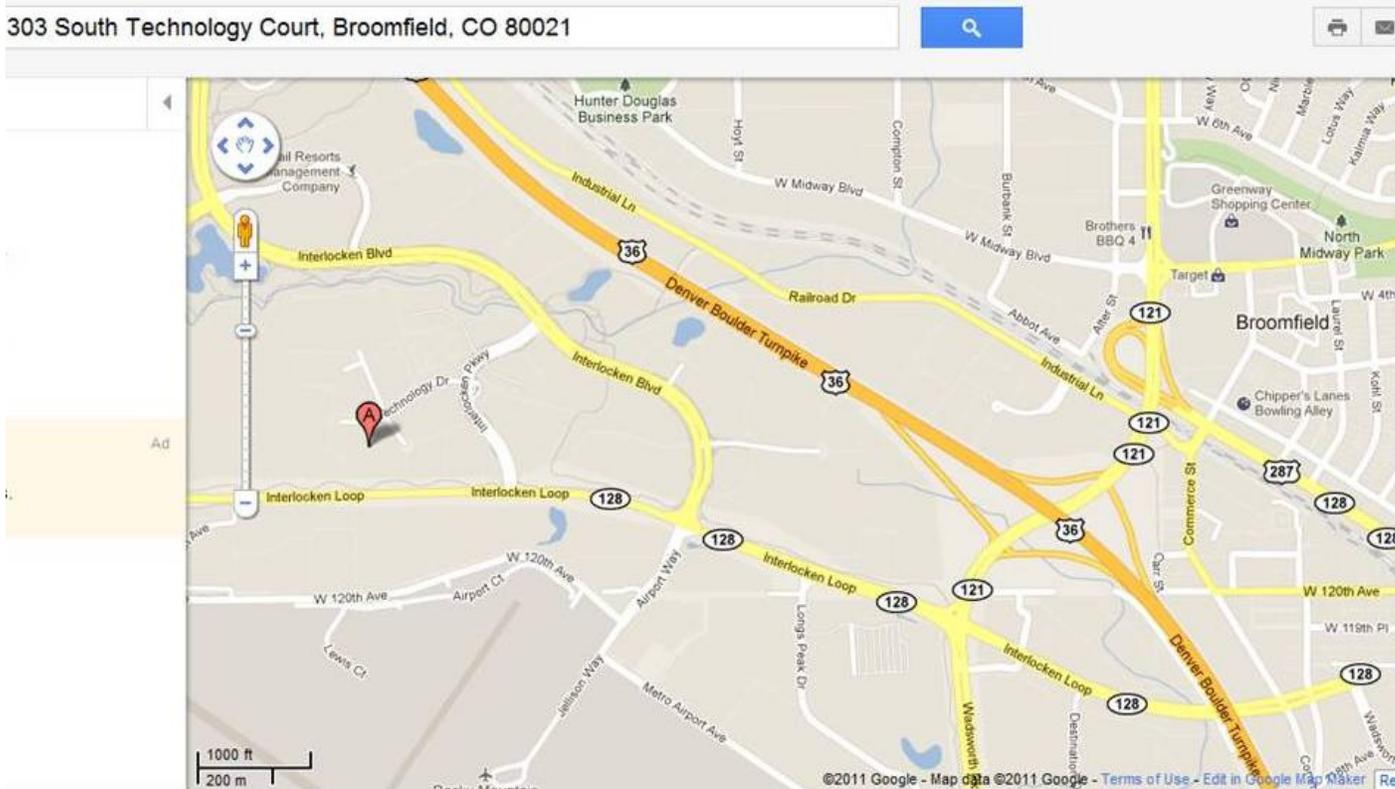
April 24th Doors open at 5:30pm at the Aircell Technology Corp in Broomfield in the “Pikes Peak Conference Room”. See map below, where the **Red A** is located.

5:30 pm: Networking and refreshments served

~ 6:05 PM “Quality Case-Studies” Presenters are John Beachman, QE of Covidien Corp/Boulder and Joe Wojniak, QE of Aircell Technology Corp. and with interaction with attendees.

Map to Aircell Corporation, Conference Room in Building A. Note: Colorado Hwy 121 in the map is Wadsworth Blvd. south of Broomfield, and Hwy 287 north of Broomfield

303 South Technology Court, Broomfield, CO 80021



If you have not been there before, we suggest that you plan to arrive in the Interlocken area about 15 min early to ensure finding the Aircell Corp Building A.

From the Boulder Section Programs Chair

Concerning meetings' speakers/lecturers...have you ever thought of presenting a case study or a problem resolution? Or, have you thought of presenting a problem and asking for possible solutions from your com-patriots? Here is your opportunity! Your “presentation” doesn't have to be a presentation and it doesn't have to take an hour. You will find that we all have similar experiences and problems to share and are willing to listen. You also will earn 1.0 recertification (RU) credits! Give it some thought and contact me if you are interested. Best Regards, Dan Clark dpclark@live.com

RMPEX For information on the Rocky Mountain Performance Excellence Program (*which is also the Colorado State Quality and Business Performance Program*), please see page 20 of this newsletter for the most recent information on upcoming RMPEX activities and events. The Boulder ASQ Section is an active sponsor of the RMPEX Organization.

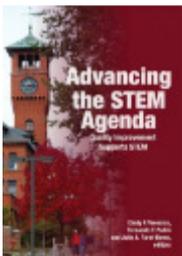
RMRAS Rocky Mountain Regulatory Affairs Society <http://rmras.org/> The RMRAS is the premier professional society in Denver-front range area for individuals involved in medical device or pharmaceutical industries. Membership is free of charge. Our societies' RU's are reciprocal and interchangeable.

News continued from page 1

ASQ National –and- Local ASQ Sections' News

New From ASQ Quality Press Order at: 800-248-1946

ASQ Quality Press books can be ordered online, or for special pricing on orders of 10 or more call ASQ Customer Care / Quality Press Bookstore at: 800-248-1946.



New Book!

[Quality Improvement Supports STEM](#)

Cindy P. Veenstra, Fernando F. Padró, and Julie A. Furst-Bowe

In July 2011, the ASQ Education Division held its first STEM Agenda Conference. This publication is a selection of the conference papers and workshops from the conference, with the theme Advancing the STEM Agenda in Education, the Workplace, and Society. The book highlights STEM education as a grassroots effort by many educators to ultimately prepare graduates for the 21st century workforce.



New certification preparation book from ASQ Quality Press

[The Certified Six Sigma Master Black Belt Handbook](#)

This book reflects the most current thinking among Six Sigma leaders who came together to create the ASQ Master Black Belt Body of Knowledge (BoK).

The primary audience for this book is the individual who plans to prepare to sit for the Six Sigma Master Black Belt certification examination. The book is great for quick reference and ease of use because the chapter and section numbering exactly mirrors that of the Master Black Belt BoK



[Best Practice in Team Excellence](#)

J.P. Russell, editing director

This book explains the Team Excellence Framework (TEF) and how to leverage it to ensure the success of your improvement teams. This framework has a long-standing track record of providing the means by which teams can produce highly successful outcomes for their organizations.

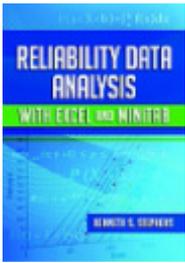


Bestseller!

[The Certified Quality Engineer Handbook, Third Edition](#)

Connie M. Borrer, editor

This third edition provides the quality professional with an updated resource that exactly follows ASQ's Certified Quality Engineer (CQE) Body of Knowledge.



Reliability Data Analysis with Excel and Minitab

Kenneth S. Stephens

When a product has been designed and manufactured, its performance in terms of durability, strength, and life become a matter of test, measurement, and analysis. This book helps you understand the outcomes of the reliability tests and translate that into real-world data that can improve products. Excel and Minitab spreadsheets are included for all sample data sets.

Updates to ASQ Recertification Journal ASQ Recertification Costs Increase in 2014

There are recent changes to the recertification journal categories, including more opportunities for RU credits, and categories have been better defined to make recertifying easier. The 18 RU credit amount remains the same. The new journal can be downloaded and printed directly from the main ASQ National website at: www.asq.org using "Certification Link" or call ASQ Customer Care at: **1-800-248-1946** and request item **B0525**

The cost of recertification recently increased due to higher costs to administer the program. This is the first cost increase in six years. Recertification by journal for members is now **\$69 for one certification** or **\$89 for two or more certifications** (e.g., if you get recertified for three areas, you pay \$89).

Anyone doing a re-certification journal through ASQ Boulder Section is strongly urged to send an e-mail to the Re-cert Chair, Gerry Naugle, BEFORE starting your journal effort, at: gnaugle@earthlink.net. There are new streamlined policies & procedure implemented which can save you *time, effort and postage*.

Boulder Section – Current ASQ Fellows

Tripp Martin – Retired
International Auto Oversight Bureau
(248) 535-5670
trippm1@earthlink.net

Ed Arling
Quality Compliance Assoc.
(303) 579-9443
edward.arling@gmail.com

Liz Keim, ASQ Past-Pres. & Board Chair
Integrated Quality Resources, LLC
(303) 541-9127
liz.keim@comcast.net

BOULDER SECTION CORRESPONDENCE ADDRESS

ASQ Boulder Section

P.O. Box 3783

Boulder, CO 80307

website is: <http://asqBoulder.org>

Note: All education & course registration materials should be sent to Section Education Chair (please see the last page of the education section for contact information)

Article on ASQ Recertification by Rebecca Jessep, ASQ Boulder Section

ASQ certification is a formal recognition by ASQ that an individual has demonstrated a proficiency within, and comprehension of, a specific body of knowledge. Nearly 150,000 certifications have been issued to dedicated professionals worldwide. An authentic professional certification is formal recognition by a respected, recognized, and established professional organization that an individual has demonstrated a proficiency within, and comprehension of, a specified body of knowledge. An ASQ certification, like most authentic professional certifications, requires that individuals demonstrate these competencies by passing an exam and having a track record of expertise in one of the

specified quality disciplines, such as Six Sigma. ASQ does not require you to take the ASQ training—or any other particular courses—as a condition of awarding such certifications.

There has been a great deal of confusion as to the true meaning of certification, especially recently, as individuals and companies strive to achieve and validate competencies in a competitive job market. Numerous training companies, educational institutions, and even individual training consultants are competing to sell training courses that purportedly include “certification.” In many cases, these are not certifications based on a noncommercial standard body of knowledge as developed by objective third-party entities, but rather paper certificates awarded for participating in specific training. While there is nothing wrong with providing evidence of a course completion (whether through a document and/or accredited continuing education units), this should not be confused with the rigor and achievement of a professional certification. ASQ offers 17 certifications. These range from Calibration Technician to Certified Quality or Reliability Engineering to Manager of Quality / Organizational Excellence. Full details on certifications can be found at:

<http://prdweb.asq.org/certification/control/right-for-you>

ASQ requires that you recertify the following certifications every three years to ensure that you maintain the same level of knowledge demonstrated in your first exam.

- Biomedical Auditor
- Calibration Technician
- HACCP Auditor
- Manager of Quality/Organizational Excellence
- Master Black Belt
- Pharmaceutical GMP Professional
- Quality Auditor
- Quality Engineer
- Reliability Engineer
- Software Quality Engineer
- Six Sigma Black Belt
- ASQ/DON Lean Six Sigma Black Belt

NOTE: Quality Inspector, Quality Improvement Associate, Quality Process Analyst, Quality Technician and Six Sigma Green Belt are lifetime certifications. They have no re-certification requirements.

There are two ways to recertify. First, you may retake the examination. Second, you can obtain 18 recertification units (RUs) within your three-year certification period and completion of your recertification journal. The recertification journal may be found on <http://prdweb.asq.org/certification/control/recertification/rucredits/index> You can accumulate credits from professional activities that increase your understanding of the Body of Knowledge or enhance your job such as employment, completed training, participation in your local ASQ chapter, etc. ASQ Section 1313's recertification chair is Gerry Naugle. Suggest calling him at: 303-591-2830 or write him at: gnaugle@earthlink.net before you send anything to him; he has some options which may save you time, effort and postage. More information and forms on certification, and re-certification at: www.asq.org

ASQ BOULDER SECTION #1313 COURSE DESCRIPTIONS

INSTRUCTORS & COURSE DESCRIPTIONS: A list of instructor biographies and course descriptions can be found on the ASQ Boulder Section web site, <http://asqBoulder.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.

2014 ASQ Boulder Section Course Offerings

Updated 04-14-2014

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

Course Name	Instructor	Course Fee (1) (2)	Exam Date	ASQ Exam Application Deadline	Course Dates & Times	Course Registration Deadline
1301 - Certified Quality Engineer (CQE) Review	Monrad Monsen 303-272-9612 Location: Contact Instructor	\$400 members / \$450 others	June 7, 2014	April 18, 2014 April 23 (late)	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631 Location: TBD	\$400 members / \$450 others	June 7, 2014	April 18, 2014 April 23 (late)	TBD	TBD
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			TBD	TBD
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			TBD	TBD
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			TBD	TBD

(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**, 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: Ron Sedlock, the quality Catalyst

If you have any quality training needs, keep me in mind. I offer a variety of quality classes such as:

- **Effective Quality Management Systems**
- **Lean Six Sigma Statistics**
- **ISO 9001 Process-Based Auditing**
- **Baldrige Criteria Assessments**
- **Service Quality**

Many of the classes are helpful for those seeking ASQ certification and/or implementing Lean Six Sigma improvement. If the you have a specific quality need, I can customize a training class to meet that need.

If you are seeking ASQ certifications I do exam preparation classes for most certifications. I recommend start preparing at least 3 months prior to any exam. For the following **June 7th** exams you should start in **March**:

- **Certified Quality Engineer (CQE)**
- **Certified Quality Auditor (CQA)**
- **Certified Six Sigma Green Belt (CSSGB)**

I offer public seminars only if the demand is there. All my training can be offered "in-house". In-house training is more cost effective if you have 6 or more trainees.

If you are planning to study alone for a certification exam, I can give you advice on the best way to prepare.

This is a free service.

Ron Sedlock the quality Catalyst phone: 303.716.5873 or 303.587.9153 (cell)

www.thequalitycatalyst.com

Colorado Quality Executive Network (CQEN)

Colorado Quality Executive Network (CQEN) <http://www.thequalitycatalyst.com>

- Meeting: Next meeting TBD

- Topic: TBD

- Speaker: Round table format

- Place: TBD

Group Information and Contact Information

- The Colorado Quality Executive Network (CQEN) is a network of people who have the top quality responsibility at organizations.

- The purpose of the network is to share ideas on what works and doesn't work in the pursuit of quality at the executive level.

- Participation in this network **is by invitation only**. - Please contact Ron Sedlock if you have an interest.

Ron Sedlock phone: 303.716.5873 or 303.587.9153 (cell) Email: ronsedlock@thequalitycatalyst.com

Rocky Mtn Regulatory Affairs Society (RMRAS) is proud to be a co-sponsor of the annual Association of Food and Drug Officials [AFDO] conference to be held in Denver, June 23-24, 2014 at the Grand Hyatt Hotel. This seminar will primarily be attended by industry representatives from the pharmaceutical and medical device community as well as federal and state regulatory officials. The RMRAS Steering Committee felt this would be an excellent opportunity to not only meet and interact with government officials, but also to learn their focus for both the medical device and pharmaceutical industries for the future.

Below is a link to their postcard with registration and agenda information:

[http://afdo.org/resources/Documents/4-news-and-events/AFDO Postcard DDC 2014.pdf?download](http://afdo.org/resources/Documents/4-news-and-events/AFDO%20Postcard%20DDC%202014.pdf?download)

Thanks! RMRAS Board

Cruisin'

ASQ Human Development and Leadership Division (HD&L) in conjunction with ASQ Greater Fort Worth Section 1416 is sponsoring the **ASQ 2014 Quality Cruise for Professional Development**. The cruise will set sail from Galveston, TX on October 26 for 8 days, 7 nights returning on November 2. Join us on the Royal Caribbean's *Navigator of the Sea* and tour the Caribbean (Cozumel, Grand Cayman and Jamaica) including 3 days at sea with morning and afternoon conference activities and presentations. Cruise with family and quality colleagues for fun and learning! For More information

[http://asqhdandl.org/uploads/3/3/3/8/3338526/qcruise fast fact sheet 20140402.pdf](http://asqhdandl.org/uploads/3/3/3/8/3338526/qcruise%20fast%20fact%20sheet%2020140402.pdf)

Quality Related Career Openings / New Job Postings



FreeWave Corp Quality Engineer

- **Job Tracking ID:** 512437-431375
- **Job Type:** Full-Time/Regular
- **Location:** Boulder, CO
- **Date Updated:** March 20, 2014
- **Job Level:** Mid Career (2+ years)
- **Years of Experience:** 5 - 7 Years
- **Level of Education:** BA/BS
- **Starting Date :** ASAP

Position Overview:

The Quality Engineer will be reporting to the Quality Manager and help drive key quality initiatives throughout the company. The main focus will be the monitoring and closure of Quality issues internally and externally, and maintaining ISO certification in addition to improving processes by monitoring key metrics.

Work will be performed at the FreeWave Technologies location in Boulder, Colorado unless otherwise specified by functional Management.

Principal Job Functions:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Work cross-functionally to ensure all ISO procedures are followed and Training Guides are utilized to standardize on and improve processes.
- Initiate and manage Non Conformance Reports (NCRs) from initial problem recognition to closure based on Field / Customer, Supplier, Manufacturing / Production, and Process issues.
- Perform internal audits to ISO procedures on a regular basis to ensure compliance to the QMS procedures for all functions at FreeWave.
- Document and maintain records in ISO Database.
- Conduct customer surveys to gauge FreeWave's performance in the eyes of customers and satisfy one of the major Quality Objectives.
- Update and revise ISO procedures and maintain in database, to improve upon processes, where deemed necessary, as a continual improvement.

- Perform assessments and audits of major component suppliers, such as suppliers of electronic modules used on FreeWave products.
- Concentrate on supplier performance and drive issues with major components to resolution.
- Prepare and support Surveillance Audits that are conducted by ISO auditors yearly.
- Provide refresh ISO training to employees in preparation for the re-certification audit and support preparation for the re-certification audit.
- Manage supplier certification surveys and approval of new suppliers and updates to existing suppliers, keeping a current list and up to date certification in the ISO database.
- Manage corrective and preventive actions to ensure Non-Conformances are addressed and closed. This task will be ongoing as Quality issues are surfaced and need to be resolved throughout the company.
- Review quality metrics and data and use statistical techniques to show trending issues for product and process improvement.
- Utilize 8D reporting method to drive corrective and preventive actions.
- Maintain Employee List in ISO database and keep current with HR training and/or certification records.
- Work with HR to ensure all employees' training is completed, verified and up to date and records in the ISO database are up to date.
- Work with Manufacturing and Engineering to implement and update Assembly Instructions on all products.
- Other duties as assigned
- Must be a US Person in accordance with United States immigration laws to be considered for this position.

Experience and Skills:

Knowledge, Skills and Abilities:

- Four to seven year experience in developing and maintaining a Quality Management System (QMS) and supporting certification to ISO 9001/AS9100.
- Excellent written and oral communication skills are required.
- Excellent organizational skills and attention to detail are required.
- Demonstrated analytical expertise including ability to plan, resolve problems effectively, and establish priorities.
- Working knowledge of Quality Management Systems (QMS) is required.
- Internal auditing skills in ISO 9001 or others is highly desired.
- Knowledge in Printed Circuit Board and/or electronics is preferred.
- Must be a US Person in accordance with United States immigration laws to be considered for this position.
- Quality minded individual with proven records of promoting Quality as a major driver for customer satisfaction and retention.
- Certified Quality Auditor is highly desired.

- Certified Quality Engineer is a plus.
- Six sigma certification is preferred.
- Demonstrated ability to work cross-functionally to drive root-cause and corrective action where needed.
- Four to seven year experience leading efforts to address quality issues in Failure Review Board (FRB)/Material Review board (MRB) forum.
- In depth knowledge with performing and reviewing Process Failure Modes and Effects Analysis (PFMEA) and ability to apply its principles and results to process improvement.
- Applied experience in Statistical Process Control (SPC), Corrective and Preventive Action (CAPA), and Lean Manufacturing is highly desired.
- To be successful in this position, the candidate must have a commitment to quality in everything they do. This means continuous improvement of activities and processes. In order to do so, the candidate must show an ability to drive to root cause and resolve issues related to that cause.

Education and Experience:

- Bachelor Degree in a technical or engineering field, or 6-10 year equivalent combination of education and experience, is required.
- Experience working in an electronic Manufacturing environment is highly desired.

Physical Demands /Work Environment:

- Work cross-functionally to drive continual improvement in product and processes.
- Able to work in a noisy Manufacturing environment on an as needed basis.

Company Description:

FreeWave Technologies provides the most reliable, high-performance spread spectrum and licensed wireless data radios for critical data transmission to oil and gas, utility, military and numerous other industries worldwide. As a market leader, we are committed to providing best-in-class radio products and unmatched customer service and support. We seek staff who are willing to help us grow and to achieve our commitments with excellence.

Our future growth requires new employees who are able to find innovative ways to contribute to the organization. We need people who are able to contribute unique skills to the team, solve problems either as a member of a team or on their own, and fully participate in achieving group results. The ideal candidate is one who is able to fit in as a member of a progressive team in a relaxed working environment.

FreeWave Technologies, Inc. engineers and manufactures certain products that are considered ITAR-controlled items under the International Traffic in Arms Regulations (ITAR). Consistent with ITAR, any position at FreeWave that involves work with the engineering or manufacturing functions of the Company may only be filled by a candidate who is (i) a citizen of the United States, or (ii) a person who has been accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws.

Quality – To be successful in this position, the candidate must have a commitment to quality in everything they do. This means continuous improvement of activities and processes. In order to do so, the candidate must show an ability to drive to root cause and resolve issues related to that cause.

EOE/M/F/V/D

Instruments Rental Labs Inc. (IRL) in Broomfield, CO

Calibration Technician

Location: Broomfield, Colorado

Duties: Electronic test and measurement equipment calibration.

Salary: Competitive and commensurate with skill and experience.

Web page: WWW.Testequip.com

Knowledge and capabilities:

- Current "CCT" (ASQ-Certified Calibration Technician) certificate.
- 5 + years of Calibration lab experience
- Operational knowledge of Fluke "Metcal" automated calibration software and interfacing procedures.
- DC, Low Frequency, Microwave, Impedance and general electrical and electronic equipment knowledge training and experience.
- Documentation experience with accredited calibration including ability to compute and construct uncertainty evaluations.

Contact: ***no calls please.***

Send your resume with salary requirements to:

BillH@testequip.com

Rocky Mountain Eye Bank (RMEB)

is an Equal Opportunity Employer 1675 Aurora Court Aurora, CO 80045 www.corneas.org

The Rocky Mountain Eye Bank's mission is to fulfill the wishes of eye donors and their families to help another overcome blindness through transplantation and research. Our dedication to this mission allows organ & tissue donors in Colorado and Wyoming to provide nearly 2,000 sight-restorative transplants each year. RMLEB is a progressive organization with a strong commitment to the achievement of excellence and diversity.

POSITION DESCRIPTION:

JOB TITLE: Quality Assurance Coordinator

JOB CLASSIFICATION: Full-time, non-exempt

LOCATION OF POSITION: Aurora Office

THIS POSITION REPORTS TO: Quality Assurance Manager

SUMMARY STATEMENT: The Quality Assurance Coordinator assures compliance with government and industry standards. The Quality Assurance Coordinator monitors SOP/document forms, change control process, champions a continuous quality improvement process and may be the Eye Bank's OSHA representative.

ASSIGNED RESPONSIBILITIES AND DUTIES:

- Receiving and investigating departures, deviations and corrective actions
 - Follow-up and tracking corrective action effectiveness
 - As needed assist with SOP/document change control process
 - Assist with records retention control
 - Monitor equipment verification, maintenance, and cleaning records
 - Perform activities associated with inspections, audits, monitoring, and trending
 - Review / audit records and procedures for completeness, accuracy, and compliance
 - Activities associated with vendors and contracted service providers - agreements, off site audits
 - Review donor records for completeness, accuracy and data collection after distribution
 - Perform customer service tasks with current and potential surgeons
 - Assist with or conduct new surgeon orientation
 - Receive, investigate and evaluate information to include complaints and donor new information
 - Assist in managing adverse reactions/events and complaint trends
 - Follow-up and data entry of pending recipient information for transplanted tissues, including Recipient Information Forms and Recipient Post-operative Follow-up Forms
 - Provide feedback and training to technical staff related to chart completeness and accuracy
 - Provide new employee safety training
 - Assess organizational training needs as part of a team; design, coordinate and implement training programs
 - Assist in compiling, disseminating, and examining statistical data as directed
 - Complete Department of Health Serology Reporting.
- Perform other duties as necessary and as assigned by management

QUALIFICATION REQUIREMENTS:

EDUCATION: A Bachelor's degree in a science related field is required. Appropriate regulated industry experience or certification may be substituted for education. Thorough knowledge of ocular anatomy and physiology as well as medical and medical terminology knowledge is needed to understand aspects of eye banking.

EXPERIENCE: The Quality Assurance Coordinator should have at least 2 years experience working in a regulated industry. Knowledge and experience with FDA regulations and quality systems (cGTP or cGMP) is a must. An understanding of auditing practices and basic statistical analysis is needed. Familiarity with EBAA or AATB medical standards is a plus.

The Coordinator should have experience working with quality systems / programs, preferably in eye or tissue banking, medical diagnostics, medical devices or other medical areas. Consideration will be given to candidates with equivalent experience or knowledge from a cross-over profession or industry. The Coordinator should be familiar with MS Office, donor databases and electronic quality databases. The Coordinator is responsible for performing administrative aspects that may include interaction with or within the Technical, Quality, Public Relations and Accounting Departments. The position requires excellent people skills, as well as effective written and verbal skills for both internal and external communication. The Coordinator may be asked to develop and maintain business relationships with surgeons, surgery sites and their staff in an effort to open communication channels for reliable quality monitoring. The specific training is provided by the managers of each department where applicable.

COMPENSATION:

Salary Range is dependent upon experience.

RMLEB provides a full benefits package to include healthcare, dental, vision, 401k, holidays, paid time off and flexible scheduling.

Resumes must be accompanied by a cover letter explaining how the applicant meets the job requirements and desired skills. Please email cover letter and resumes to swolff@corneas.org with applicant name and the job title listing in the subject line. No phone calls, please.

The deadline for application submission is April 29, 2014.

Terumo BCT, Inc.
10811 West Collins Avenue

Lakewood, CO 80215 Phone: 303.231.4357 Fax: 303.542.5215

Terumo BCT
Sr. Regulatory Affairs Specialist

Working without significant direction, provides leadership to the Company in fulfilling regulatory compliance by applying a thorough understanding of regulatory/standards requirements to one or more areas of expertise such as FDA regulations, international medical device regulations, product reimbursement, product liability, and standards.

ESSENTIAL DUTIES

- Assumes major responsibility for one or more major regulatory affairs areas based on past experience and a broad base of knowledge and understanding of regulatory requirements.
- Interacts with and/or directs others in interacting with regulatory and certification authorities. Identifies the need for, prepares, and conducts regulatory related training for the business.
- Identifies and defines contents for regulatory submissions/dossiers. Leads the assembly and creation of these documents for their timely submission to regulatory authorities.
- Advises business management of regulatory and certification issues in a pro-active manner.
- Exercises considerable judgment in determining approach and then researches, prepares, and submits required regulatory documents including those in response to documents issued by regulatory authorities. Responsibility includes both preparation of these documents in compliance with U.S. and international regulatory authorities and providing guidance to Regulatory staff in the preparation of them.
- Provides regulatory support of clinical trials.

MINIMUM QUALIFICATION REQUIREMENTS

Education

Bachelor's degree or, equivalent of education and experience sufficient to successfully perform the essential functions of the job may be considered.

Experience

Minimum 5 years experience.

Skills

- **Pharmaceutical, or medical device regulatory experience desired.**
- **Familiarity with developing IDE, IND, NDA, ANDA 510(k) or PMA US FDA applications desired.**
- Experience with design control systems and project team experience a plus.
- Knowledge and use of relevant PC software applications and skills to use them effectively.
- Demonstrated ability to communicate effectively both verbally and in writing.
- In depth knowledge of U.S. and/or international medical device regulations and standards.
- Extensive knowledge of and ability to prepare regulatory documentation.
- Proven effective leadership and team skills. Strong interpersonal skills.
- Demonstrated ability to define problems and provide guidance to management in developing and implementing solutions.
- Analytical and creative thinking skills and the ability to solve complex problems.

-Or-

An equivalent competency level acquired through a variation of these qualifications may be considered.

PHYSICAL REQUIREMENTS

Typical Office Environment requirements include: reading, speaking, hearing, close vision, walking, bending, sitting, and occasional lifting up to 20 pounds.

The physical demands described here are representative of those that must be met by an associate to successfully perform the essential duties of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

We are proud to be an Equal Opportunity Affirmative Action Employer. All applicants will be afforded equal opportunity without discrimination because of race, color, religion, sex, sexual orientation, marital status, order of protection status, national origin or ancestry, citizenship status, age, physical or mental disability unrelated to ability, military status or an unfavorable discharge from military service.

We maintain a drug-free workplace and perform pre-employment substance abuse testing and background verification checks.

For more information about Terumo BCT and to apply, visit our website www.terumobct.com/careers. Go to the careers section and apply to requisition JB-1970

Join Terumo BCT as we unlock the potential of blood. We are the world leader in blood component technology, delivering products, services and solutions for customers and their patients worldwide. Through collaboration with our customers and a commitment to innovation, we are the only company with the unique combination of apheresis, manual and automated whole blood processing and pathogen reduction technologies coupled with robust technology, innovation and core competencies in therapeutic apheresis, cell collections and cell processing.

As the largest medical device manufacturing company headquartered in Colorado we operate in 120 countries with more than 4,800 associates around the world.

Our company has been voted and recognized as a:

- Top five world-class training organization by *Training and Development Magazine* (2011 & 2012)

Our award-winning culture embraces:

- Leading technology through innovation and R&D
- Wellness programs
- Commitment to quality
- An environment that values and respects your individual contributions
- A philosophy of intentional growth

[Click Here](#) to see what our associates have to say about our culture.

Each associate has a positive impact on our future by:

- Connecting to the lives of the patients we ultimately serve
- Growing through professional and leadership development activities
- Sharing company success through incentive plans

DAVID SERTL, M.S., RAC, CQA dsertl1@cs.com Colorado

<http://www.linkedin.com/in/davesertl>

Quality and Regulatory Scientist

A versatile scientist with a unique understanding of both analytical chemistry and regulatory affairs and their relationship to the quality of FDA-regulated products. Specializing in regulatory requirements for the validation of analytical methods throughout the drug approval process. Utilizing critical thinking, networking and organizational skills to solve problems and move projects to successful completion. Contributing to inter-departmental teams resulting in the successful development and commercialization of 5 new regulated products generating >\$200M/year in sales.

Recent training in quality and CMC regulatory compliance during the development cycle of biopharmaceutical products.

- Stages of Method Validation • Quality Investigations • Critical Thinking
- Drug Approval Process • Root Cause, Corrective Actions • Technical Review
- Regulatory Compliance • Study Design, Data Review • Networking, Collaborating

Career Summary and Accomplishments

CONSULTANT Quality and Regulatory Affairs for FDA-regulated products 2009 - present

- Multiple contract positions in regulatory affairs and quality compliance for drugs and combination products.
- Ongoing professional development activities, training and certifications in regulatory affairs and quality.

Quality Investigator Chemical Quality, HOSPIRA, Rocky Mount, NC (Contract thru Oxford) 2013

Hospira Rocky Mount is one of the world's largest manufacturers of sterile, injectable drugs in a variety of delivery systems.

- Performed investigations of out-of-specification (OOS) results per FDA regulatory requirements (21 CFR 211.192).
- Provided critical support to a vital quality investigation yielding corrective action that reduced delays in the manufacture, release and distribution of the # 1 selling sterile product made at the Rocky Mount facility.
- Completed a Phase 1 investigation eliminating laboratory error as the source of OOS potency result for a drug product.
- Collaborated with analysts and lab management to gather information related to analyses yielding OOS testing results.
- Utilized TrackWise software to research quality issues and trending as well as to document the results of investigations.

QC Analytical Data Reviewer Quality Control, HOSPIRA, Boulder, CO (Contract thru Kelly) 2012

Hired to help with FDA compliance remediation project at Hospira Boulder (which manufactures pharmaceutical APIs).

- Trained to perform full technical review of QC stability data in compliance with cGMP requirements (21 CFR 211.194).
- Reviewed analytical data - verifying correct methods were run and good documentation practices were followed.
- Verified that methods were performed properly, that results were calculated correctly and compared with specifications.

Regulatory Compliance Specialist AEROPHASE INC., Longmont, Colorado (Contract) 2011

Aerophase is a drug/device company working to commercialize a device for the targeted delivery of chemotherapy drugs.

- Evaluated the current status of their technology and regulatory compliance activities needed to attract investors.
- Identified and engaged an expert consultant to train in how to communicate with potential investors.
- Coordinated multiple meetings with the consultant resulting in Aerophase being better prepared to gain investors.

Regulatory Affairs Intern CBR INTERNATIONAL, Boulder, CO (10 week paid Internship) 2010

CBR is a regulatory affairs consulting company providing integrated program and strategic development services.

- Assisted in the preparation, QC review and submission of IND amendments to the FDA on behalf of clients.
- Performed regulatory research for changes in legislation, regulations and current regulatory agency thinking.
- Prepared slide sets, information sheets and templates regarding key regulatory topics for client or internal use.

David Sertl Quality & Regulatory Scientist page 2 of 2

Ongoing Professional Development Colorado and international professional organizations 2009 - present
Training, certifications and networking activities to broaden skills and areas of understanding and expertise ...

- Trained in principles of quality auditing and earned the ASQ CQA certification (Certified Quality Auditor).
- Utilized online and local resources to study and Earn the RAC certification in U.S. regulatory affairs for drugs and devices.

- Completed 13 online courses, Earned the Pharmaceutical Certificate Regulatory Affairs Professional Society (RAPS)
 - Completed 2 certificate courses in GLP and GMP for medical devices at the University of Denver.
 - Studying the CMC regulatory aspects of the development and approval process of biopharmaceutical drugs.
 - Networking with experts and professional meetings to increase understanding of quality and regulatory affairs.
- Analytical Chemist, Research & Development, RENTECH INC., Denver, CO 2002 - 2008
 Rentech is commercializing the Fischer-Tropsch (F-T) catalytic process to produce clean fuels from coal and natural gas.
- Owned and managed all aspects of analytical chemistry support to R&D work into the F-T catalytic process.
 - Optimized an in-process test method to reduce testing time by 50% and increase the data produced by 100%.
 - Produced and organized analytical data to dramatically increase understanding of F-T reactor products.
 - Maintained and kept operational a key GC testing instrument to provide 24/7 availability to researchers.
 - Troubleshooting and improvement of GC methods for the analysis of hydrocarbons from reactor streams.
- Chemist, Analytical R&D, Ross Products Division, ABBOTT LABORATORIES, Columbus, OH 13 years pre-2002
 The Ross Products division of Abbott develops and manufactures infant formula and adult medical nutritional products.
- Provided key analytical testing support to development of 5 nutritional products generating >\$200M/yr in new sales.
 - Innovated to develop a critical in-process test that enabled manufacturing of a new line of nutritional products.
 - Optimized numerous analytical methods to significantly improve performance and reduce testing time and costs.
 - Evaluated and adopted 2 new analytical technologies (Near-IR, Dionex HPLC) to provide new testing capabilities.
 - Developed, validated and implemented 5 major analytical methods for FDA-regulated nutritional products.
 - Managed complex technical projects to support the quality of new products in development.
 - _ Developed and validated analytical methods for critical quality attributes of nutritionals.
 - _ Wrote technical reports and publications, organized data and communicated test results to customers.
 - Investigated the quality of testing method and out-of-specification (OOS) test results, implemented corrective actions.

Education and Certifications

Certified Quality Auditor (CQA) certification American Society for Quality (ASQ) 2013
 RAC(US) Regulatory Affairs Certification Regulatory Affairs Professional Society (RAPS) 2010
 Pharmaceutical Certificate (9 courses in regulatory affairs) RAPS 2009
 Certificate courses in GLP and GMP for medical devices, Denver University 2009
 Masters degree in Chemistry, Cornell University Bachelors degree in Chemistry, Union College
 Top Talents
 Critical Thinking (to evaluate, investigate, improve)
 Networking (to gather needed information)
 Organizing Data (seeing relationships and presenting information)
 Accomplishments
 Received Abbott Presidential awards for cost savings and excellence in support of international manufacturing.
 Provided analytical support to the successful development of 5 multi-\$M products in an FDA-regulated industry.
 Developed an HPLC method for Vitamin D in infant formula - later adopted by the FDA for compliance testing.
 Computer skills Microsoft Office (Word, Excel, PowerPoint,) TrackWise software (writer, reviewer, approver)

Message from the Chair

By: Jeanne Brown

UPCOMING EVENTS

Our Mission

RMPEx guides organizations and volunteers to performance excellence by providing education, training, networking, and sharing of best practices leading to assessment and feedback, which result in continuous improvement, recognition, and awards.

Upcoming Events

Examiner Training Dates



Healthcare Sector

TIMBERLINE AWARD LEVEL Sky Ridge Medical Center City of Fort Collins

These two organizations demonstrated systematic and mature approaches, effective deployment, process learning, and process integration.

Award recipients, as well as examiners and judges who volunteered countless hours, will be honored at the 2014 Quest for Excellence conference in Littleton, CO on April 18, 2014. This event provides a rare opportunity to learn from the pro's who have led large-scale organizational transformation. The Quest event will include national Baldrige recipients and local recipients who will share their insights on continuous improvement utilizing the Baldrige framework. Mark your calendars now and look for more details as the event grows near.

Here's to continuing the journey toward performance excellence in 2014 and beyond !!

Respectfully,
Board Chair: [Jeanne Brown](#)
Executive Director: [Kim Griffiths](#)
Award Program Facilitator: [Jim Walker](#)



Baldrige News

Baldrige's 26th Anniversary

[Register today for the 26th annual Quest for Excellence® conference and learn how to improve your organization's performance from 27 Baldrige Award-winning organizations! ...\[Learn more\]\(#\)](#)

Baldrige Director Harry Hertz Retires

After 21 years, Baldrige Director Harry Hertz will be leaving the position on June 3, 2013...[Read more](#)

Look Who's Using Baldrige: A Focus on Southeast Asia

"No one could be a prophet in his own country." (Dejavu Dr. Deming and Dr. Shewhart) says Bill Voravuth Chongsuanimit, Lead Assessor of the Thailand Quality Award...[Read more](#)

News

Innovation and Cross-Sector Learning

Recently, Russell Gonnering wrote a piece in *Physician Executive* entitled "Health Care Can't Wait to Innovate" that explored innovation through the example of jet propulsion...[Read more.](#)

Why Baldrige? Ask Leaders of Top U.S. Hospitals

Two years ago, a Thomson Reuters study found that health care organizations that won a Baldrige Award or received a site visit during the Baldrige Award process outperformed.



Service Sector News

Plates Still Spin but Senior Leaders Find Peace of Mind

Over the last sixteen years, Turner Broadcasting System, Inc., has seen millions of dollars of cost savings through a focus on continuous improvement that drives efficiencies and innovation...[Read more.](#)