

Volume 26, Issue 4

April 2019

APRIL CHAIR MESSAGE

April's speaker, Rod Sedlock, is presenting a rather interesting topic- what's after Six Sigma? Has Six Sigma run its course? Several Six Sigma proponents have incorporated Lean (Toyota Production System) into Six Sigma to produce Lean Six Sigma. SSD Global has introduced Leaner Six Sigma. What might be the next evolution of Six Sigma or will it be replaced by something else? I hope you come to hear Ron's presentation to find out.

A brief history of Six Sigma:

1980's	Six Sigma is developed at Motorola
1990's	Six Sigma is popularized (Texas Instruments, GE, Allied Signal)
2000's	Jack Welch makes 6-Sigma priority at GE
2010's	continued adoption
2020's	widespread use
2020's	TBD

https://en.wikipedia.org/wiki/Six_Sigma

To learn more about Six Sigma:

<https://medium.com/swlh/is-six-sigma-dead-7025390be6a7>

<https://pcb.com/article/six-sigma-a-case-study-in-motorola>

<https://www.isixsigma.com/new-to-six-sigma/history/history-six-sigma/>

Section Meeting Overview:

April - Topic: After Six Sigma: What's Next? Ron Sedlock
May - Topic: Quality Tour – TBD
June - August: Summer break
September - Topic: What it Takes to Become a LSSBB, Dan Clark

Quality Tours! Please contact me or Dan Clark if you're interested in giving a tour. Here is a list of a few companies that have provided tours- you could be one of them! PTA Plastics, REO (Research Electro-Optics), Fed Ex, Boulder Scientific, Medtronic Surgical Navigation ... and many more!

We have new ways of staying connected, please "like" the Section 1313 Facebook page and post an update introducing yourself to fellow Quality professionals:

<https://www.facebook.com/ASQBoulder/>

We also have the MeetUp- it helps to RSVP so that we help sites that are hosting tours how many people to expect, etc.

<https://www.meetup.com/Boulder-Quality-Meetup/events/256648826/>

Best Regards, Joe Wojniak

ASQ Section 1313 Chair joe.wojniak@gmail.com

ASQ's Members and Customers 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(s) links, books, courses, yearly certification testing, re-certifications, conferences, ASQ Divisions and on-line membership forms which include member upgrades and that which is needed to update your own member profile. And, while you are on the internet, be sure to visit the ASQ Boulder Section website at: <http://asqboulder.org>

ASQ National News

April ASQ Member Gift

Whether it's internal operations, ISO compliance, or supplier management, auditing plays a key role to assure that systems are not only optimized for meeting output goals but also improving to stay competitive in the marketplace. Toward these ends, we're sharing resources on implementing and auditing to ISO 9001, ISO 14001, and ISO 45001 and beyond, including videos, new webcasts, a complete free eBook on ISO 9001: 2015, and lots of additional articles, tools, and templates.

We hope you enjoy it, and it serves to prepare you for your next continuous improvement challenge. Enjoy

Looking for ways to earn recertification units (RUs)? Viewing all the webcasts in this month's member gift equals approximately 6.5 hours (or 0.65 RUs) of home study activity under courses. Visit asq.org/cert/recertification for details.

Your exclusive member content bundle will be available through April 30, 2019.

ASQ National (and) Boulder Section News is continued on page 4

ASQ #1313 Officers & Committee Chairs 2019

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ASQ Section 1313		Boulder, CO	
Title: Section Chair Name: Joe Wojniak section1313chair@gmail.com	Title: Vice Chair Name: Albert Vergara Phone: 623 640 4601 albert.vergara.948@gmail.com		
Title: Secretary Name: Bill Dunford Phone 720-340-0454 bdunfordASQ@gmail.com	Title: Treasurer Name : Caroline Corwine Phone : 303-912-7327 carolinecorwine@yahoo.com		
Title: Re-Certification Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Internet & Website Name: Arnold Miller Phone: 303-466-2631 arnold.miller0@gmail.com		
Title: Publicity and VOC Name: Byron Murray byron.murray@yahoo.com	Title: Education Chair Name: Dan Clark Phone: 720-326-8240 dpclark@live.com		
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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 bdunfordASQ@gmail.com		
Title: Certification Name: Phone:	Title: Program Chair Name: Dan Clark Phone: 720-326-8240 dpclark@live.com		

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PROFESSIONAL COMMUNITIES FOR NETWORKING AND DEVELOPMENT

Connect with ASQ Communities

ASQ communities help you connect with members and other quality professionals in your geographic area, your industry, or with your interests.

- **Geographic communities** are formed based on where members live. They are member-led communities that include sections and subsections in the U.S. and Canada, country counselors in more than 40 countries around the world, and local member communities outside the U.S. and Canada. Student branches can be found at educational institutions around the world.
- **Topic and industry-specific communities** are formed based on member interests. They are member-led communities that include divisions, forums, interest groups, and technical communities.
- **Online communities** provide expanded networking and learning opportunities no matter what your location, industry, or topic interests may be. Can't find what you're looking for? Members can create new communities to generate new discussions and connections. Anyone can join online communities to reach a broader audience of quality professionals and practitioners – anytime, anywhere.
- **Social media** – follow ASQ on a number of popular social media platforms.
- **Blogs** – follow ASQ influential bloggers, the View from the Q, and a variety of blogs in our online communities.

Questions about communities? Contact [Community Development](#).

Visit the ASQ Website to Network

Upcoming ASQ Boulder Section Meeting, Thurs, April 25th

Location: Frasier Healthcare, 350 Ponca Place Boulder, CO 80303 (map below).

5:30pm Doors Open: networking 6:00pm pre-meeting, 6:10pm presentation 7:45pm Meeting Finished

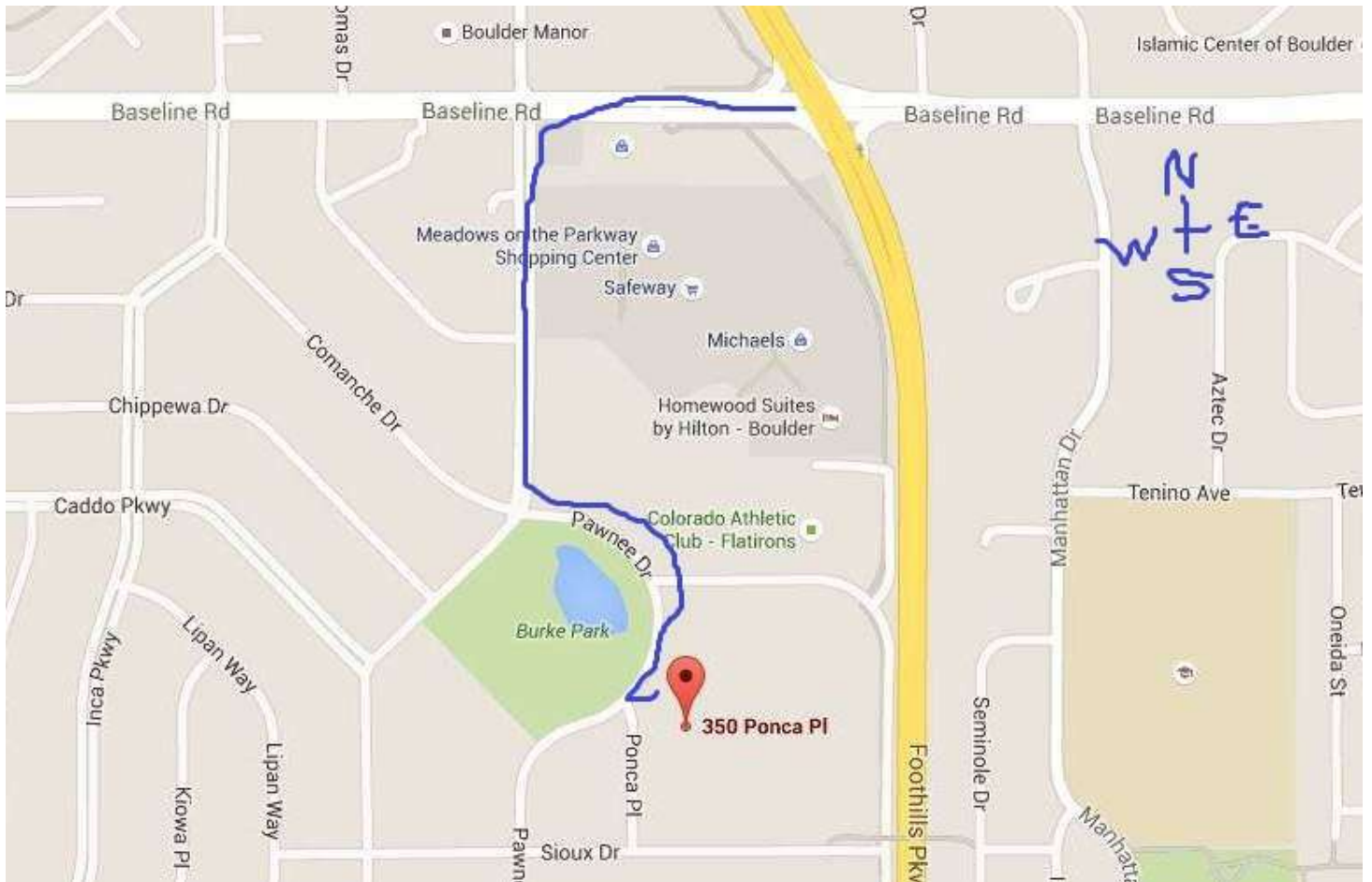
Presenter: Ron Sedlock, quality Catalyst (see page 10)

Topic: After Six Sigma: What's Next?

Abstract: During the presentation, Ron his will discuss current Six Sigma topics, and also about the value of ASQ certification. Added information and background on the career of Dr. W. Edwards Deming.

Ed note: This is a must-see.

Frasier Meadows is where the **Red A** is. From Baseline Road take **Mohawk Drive, and turn left (south) on to Pawnee Drive** at the big-ship-anchor of USN Admiral Arleigh Burke's Park. Follow Pawnee Drive east around that park to 350 Ponca Place. At that point, you can't miss the Frasier Meadows Healthcare on the east side of the street. Please go in the main doors, and sign into the building in the book on small desk just inside the doors. Veer right past the main desk, go about 70 feet east of the desk to the main elevators, take an elevator **to the ground floor**, and walk north in the hallway about 400 feet. Then veer left to the hallway is where the North Community Meeting room is located, where we have our ASQ Meetings.



ASQ National – and – Local ASQ Section’s News

ASQ COMPUTER-BASED CERTIFICATION TESTING



Review our test policies and procedures



Experience a computer-based test with this CBT walk-through



Locate a test center and **schedule** your appointment



How to **schedule** your appointment on the Prometric website



Learn what to expect at the test center (*video**)

*This video from Prometric depicts an average testing day, ASQ does not require biometric testing.

Recertification is easier now too.....see next page for the news on re-certs.



Dear Certification Holder,

Keeping your ASQ certification current is key to continuing your professional development, staying up to date within your industry with new and relevant knowledge, and maintaining your credibility in a competitive work environment. And now, recertification is easier than ever using ASQ's new online application process. The recertification online application is user-friendly, secure and more efficient—saving you time, effort and expense—and is available 24/7 from the convenience of your home. As a reminder, ASQ now requires all recertification to be processed through the new online portal.

Specifically, the new process will:

- Deliver consistency in processing
- Reduce recertification processing time to 7-10 business days
- Reduce security concerns about personal data and financial information
- Eliminate extra time and cost incurred with mail
- Provide a dashboard for your RUs
- Offer simple drag-and-drop document upload
- Archive a complete document history

The online application also will automatically integrate recertification units directly into your account for activities such as ASQ membership and certification.

The changes will provide customers with greater value and a more consistent, rewarding experience. To view the new application, click [here](#) and sign in to your account.



600 N. Plankinton Ave.
Milwaukee, WI 53203
t: 414-272-8575
800-248-1946
f: 414-272-1734
asq.org

CONNECT With Quality Leaders and Peers:



Boulder Section's Current ASQ Fellows

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

Edward 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

Advertise in the ASQ Boulder Section e-newsletter in 2019-20!

Effectively get your company (or) organization's information out in front of Boulder, Broomfield and Denver Counties QA Professionals.

<u>Number of Issues</u>	<u>¼ Page</u>	<u>½ Page</u>
One Issue (month)	\$20	\$30
Eight Issues (year)	\$50	\$80

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

BOULDER SECTION CORRESPONDENCE ADDRESS

ASQ Boulder Section
P.O. Box 3783
Boulder, CO 80307

The section website for much information and resources' links' is: <http://asqBoulder.org>

The screenshot displays the ASQ Boulder Section website interface. At the top left, a green banner asks "WHAT DO YOU WANT TO DO?". Below this, there are two main columns of options: "BUILD MY EXPERTISE" (with sub-sections LEARN, CERTIFY, and CONNECT) and "DEVELOP MY ORGANIZATION" (with sub-sections ORGANIZATION). To the right, a blue banner promotes "RECRUIT A NEW ASQ MEMBER AND EARN ASQ BUCKS." with a "LEARN MORE" button. Below that, another banner says "Download the Member Gift" with another "LEARN MORE" button. The background of the right side shows a person's hands typing on a laptop keyboard.

Upcoming Opportunities:

The ASQ Quality Management Division is requesting articles for the Quality Forum, a peer reviewed journal that 20,000 Quality professionals receive 2 times a year to ASQ's worldwide membership. Please contact me for details (joe.wojniak@gmail.com.)

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.

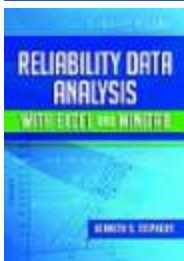


Bestseller!

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.

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, **Dan Clark**, Phone: (720) 326-8240 to see if the class you want can be made available in the Denver-North Loveland or Ft. Collins area.

2019 ASQ Boulder Section Course Offerings

Updated 10Apr2019

Course Name	Instructor	Course Fee ^{(1) (2)}	Testing Window ⁽³⁾	ASQ Exam Application Deadline	Course Dates & Times	Course Registration Deadline
1301 - Certified Quality Engineer (CQE) Review	Monrad Monsen 303-272-9612	\$400 members / \$450 others	June 7 - 23, 2019	May 10, 2019	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631	\$400 members / \$450 others	June 7 - 23, 2019	May 10, 2019	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.
- (3) See ASQ webpage for other certifications and test window dates. <http://asq.org/cert/dates>
- (4) Contact the Boulder Education Chair, Dan Clark (720) 326-8240 <http://asqBoulder.org> 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 #: _____

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 send check to: **ASQ-Boulder Education c/o Boulder ASQ Section P.O. Box 3783 Boulder, CO 80307**

and contact **the Boulder Section Education Chair Dan Clark**, Phone: (720) 326-8240 (e-mail information on page 2) to reserve your spot in the course that you want.

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

ASQ Certification Advice

If you are planning to take an ASQ Certification exam and studying on your own, I give advice on the best way to do that. This is a FREE service. It is my way of giving back to the profession that has served me well for over 40 years.

Phone, Text or Email: 303.587.9153 or rsedlock@msn.com

Cavendish Scott, Inc.

Cavendish Scott is the Rocky Mountain Region's primary ISO 9001:2015 training, consulting and auditing organization. They have given many presentations and workshops to ASQ members. Cavendish Scott, Inc. is the only US organization to have IRCA Certified ISO 9001:2015 Lead Auditor and "ISO-Transition Training" available.

ISO 9001:2015 Lead Auditor/IRCA ISO 9001:2015 Lead Auditor Training, Denver: IRCA training focuses on successfully learning the requirements of the new standard and new auditing techniques and skills. It demands an activity based learning environment – not death by PowerPoint. Learn the new standard and how it will be audited. Now is the time to make your plan and get your quality team registered for classes so they can fully understand the newest standard. Call for class starts in 2018.

ISO 9001:2015 Transition Training: The first step in addressing ISO 9001:2015 and upgrading your certification is a comprehensive review of the standard. Cavendish Scott, Inc., is presenting a one day intensive workshop to do just that. You will understand the requirements of the standard, their application, how they will be audited and implementation approaches. Solutions systems, best practices, and implementation plans will be discussed. Call for class starts in 2018.

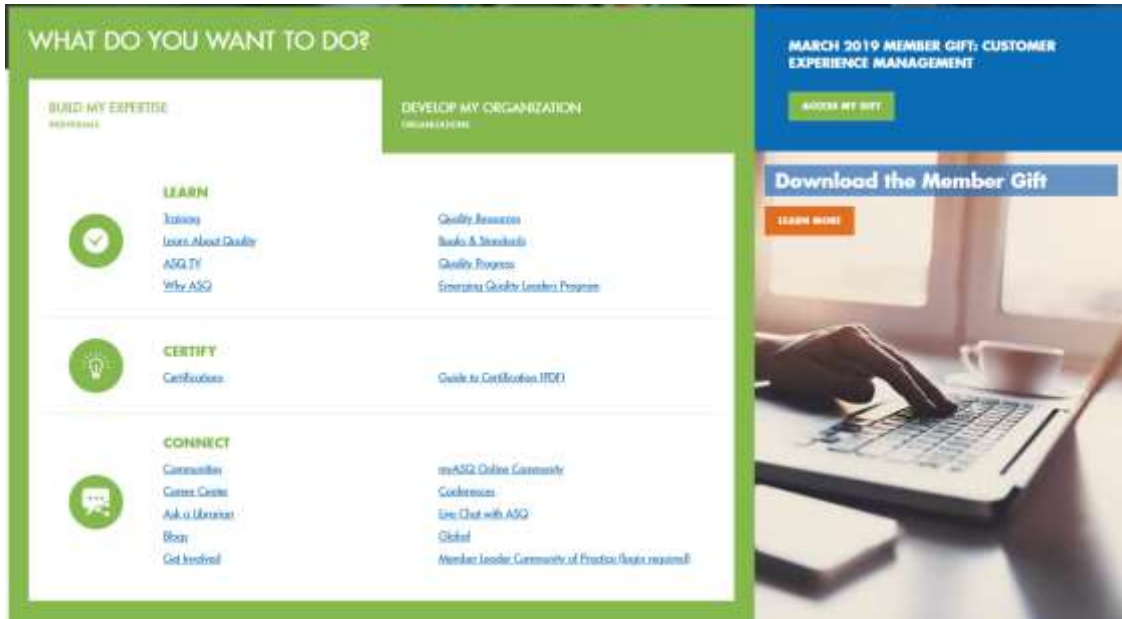
984 S Vine St. Denver, CO 80209

phone: (303) 480-0111

RMPEx Rocky Mountain Performance Excellence Program, which is also the Colorado State Quality (and) Business Performance Award Program. It is based on the Baldrige Criteria. (below)

RMRAS Rocky Mountain Regulatory Affairs Society. RMRAS is the premier local professional society in the Denver & Front Range area for individuals involved in medical devices or pharmaceutical industries. Membership is free of charge. And, our two societies' recertification units (RU's) are reciprocal and interchangeable. <http://rmmas.org/>

Don't Forget to access your Member Gift Online



The screenshot shows a website interface with a green header and a blue sidebar. The main content area is divided into two columns: 'BUILD MY EXPERTISE' and 'DEVELOP MY ORGANIZATION'. The 'BUILD MY EXPERTISE' column has three sections: 'LEARN', 'CERTIFY', and 'CONNECT'. The 'DEVELOP MY ORGANIZATION' column has a 'Quality Resources' section. A blue sidebar on the right contains the text 'MARCH 2019 MEMBER GIFT: CUSTOMER EXPERIENCE MANAGEMENT' and a 'ACCESS MY GIFT' button. Below this is a 'Download the Member Gift' section with a 'LEARN MORE' button. A blue arrow points from the top right towards the 'ACCESS MY GIFT' button.

WHAT DO YOU WANT TO DO?

BUILD MY EXPERTISE
MEMBERSHIP

LEARN

- Training
- Learn About Quality
- ASQ TV
- Why ASQ

CERTIFY

- Certifications

CONNECT

- Communities
- Career Center
- Ask a Librarian
- Blog
- Get Involved

DEVELOP MY ORGANIZATION
ORGANIZATION

Quality Resources

- Books & Standards
- Quality Programs
- Emerging Quality Leaders Program

MARCH 2019 MEMBER GIFT: CUSTOMER EXPERIENCE MANAGEMENT

ACCESS MY GIFT

Download the Member Gift

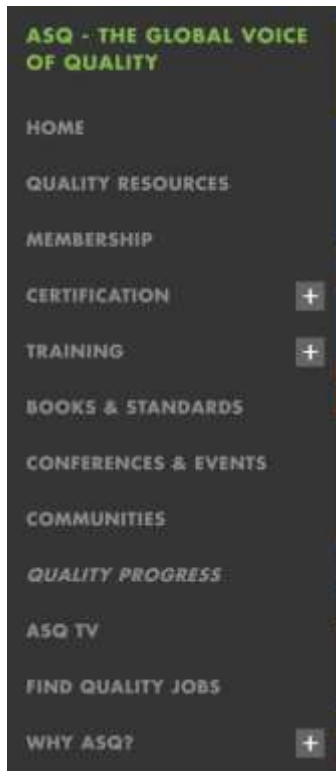
LEARN MORE

Quality-Related Career Openings / New Job Postings

ASQ National is now placing job openings by region / local / zip-code up on their website (below) The compilation is coming from various professional // social media.

Get the list from the pulldown menu on the upper left side of your home page, the click “FIND QUALITY JOBS”

Numerous Job Postings for Boulder >> Longmont >> Denver up on the “Linkedin Site” (example below)



Navigation bar: MYHOME COMMUNITIES DISCUSSIONS EVENTS NEWS VIDEO MEMBERS HELP

Welcome to myASQ

You now have access to a community that offers accessible, timely, and relevant solutions to specific issues through meaningful connections. Complete your profile and visit the "Introduce Yourself" discussion to say "Hi." As a member you have access to exclusive myASQ content.

News and Announcements

Videos

myCommunities

Rocky Mountain Orthodontics

GENERAL PURPOSE / SUMMARY OF POSITION:

Under direction of the Quality Manager, coordinates critical activities to support QMS compliance with ISO 13485, Council Directive 93/42/EEC, MDSAP, MHLW Ministerial Ordinance 169, and FDA QSR requirements. Responsible for establishing and leading the internal audit program of the quality management system. Develops audit protocols and checklists. Lead Auditor responsibilities. Acts as a consultant in quality systems requirements.

Owns product registration activities both domestically and internationally. Maintains applicable establishment registrations and coordinates with international dealers/distributors and their associated regulatory authorities to ensure RMO's product and market compliance.

Ensures corporate compliance to all required Federal, State, Local and International Regulations and Laws. Prepares all required documentation, application, and renewal of regulatory licenses, certificates, and permits for domestic and foreign entities.

Other Responsibilities / Duties:

- Coordinate efforts associated with the preparation of regulatory documents or submissions, including establishment registration, product registration, and certificates to foreign governments.
- Coordinate, prepare, or review regulatory submissions for domestic or international projects.
- Identify relevant guidance documents, international standards, or consensus standards and provide interpretive assistance.
- Interpret regulatory rules or rule changes and ensure that they are communicated through corporate policies and procedures.
- Maintain current knowledge base of existing and emerging regulations, standards, or guidance documents.
- Recommend changes to company procedures in response to changes in regulations or standards.
- Prepare or maintain technical files as necessary to obtain and sustain product approval, registration, and licenses.
- Lead and coordinate internal and/or external audits
- Lead and coordinate Corrective/Preventative Actions (CAPA)
- Prepare or direct the preparation of additional information or responses as requested by regulatory agencies.
- Escort government inspectors during inspections and provide post-inspection follow-up information as requested.
- Participates in project teams as assigned and provides guidance on regulatory matters related to document requirements, regulatory submissions and maintenance.
- Other duties as assigned.

JOB QUALIFICATIONS:

Education or Formal Training:

- Bachelors/Associates degree or equivalent work experience.
- Lead Auditor training or certification.

Knowledge, Skills and Ability:

- Excellent written and verbal communication skills required.
- Proven ability of working in a cross functional team environment.
- Must possess working knowledge of ISO 13485, CE, MDD standards
- Knowledge of Federal, State, Local, and International Regulations and Laws for Medical Device Manufacturers.

Experience:

- Minimum of 5 years of experience in a Regulatory Affairs role in a Medical Device environment.
- Must have prior CAPA and Internal Audit experience
- Must have prior product registration and export compliance experience
- Experience/knowledge of EU MDD/MDR preferred

RMO, Inc. offers a competitive salary and benefits package including:

- Medical, dental and vision insurance
- 401k with company match
- Life, personal accident, short-term and long-term disability insurance
- Benefits Plus/ Flexible Spending Accounts
- PTO upon hire
- Costco membership
- Free downtown parking

Please send your resume including **salary requirements** to sbauer@rmortho.com or fax to the HR Dept. at 303-592-8223. For more information about our company, please visit our website at www.rmortho.com. **Resumes without salary requirements may not be considered.**



JOB TITLE: Technical Engineer 3-Device Regulatory focus

Please click on link to apply:

<https://career5.successfactors.eu/sfcareer/jobreqcareer?jobId=23271&company=terumobct&username=>

JOB SUMMARY

Work requires originality and judgment in the independent evaluation, selection, and substantial adaptation and modification of standard techniques, procedures, and criteria. Performs work which requires a broad knowledge of precedents in the specialty area and a good knowledge of principles and practices of related specialties. Duties are assigned to provide experience and familiarization with engineering methods, independent thinking, and company practices and policies. Strong experience in device regulatory certifications (eg. CSA, UL, TUV, IEC, MDD. Also, experience in EMC/EMI medical device testing and materials standards compliance (RoHS, REACH, etc.).

ESSENTIAL DUTIES

- Perform independent evaluation, selection, and application in making adaptations and modifications to projects.
- Receives assigned total project leadership responsibilities on a portion of major significant projects and will be given total management responsibility for smaller projects.
- Manages and provides leadership for the functional group's development, direction, and effectiveness, adhering to organizational policies and processes and supporting overall business and corporate objectives.
- Implements and understands FDA or regulatory requirements as necessary.
- Medical and laboratory device regulatory certifications (e.g. CSA, UL, TUV, IEC, MDD, MDR)
- Applies technology principles to multiple tasks. Working knowledge of cross-functional and related technical areas.
- Highlights risks and understands how to approach and complete tasks, avoiding serious delays and considerable expenditure of time and resources.
- Advises team members pro-actively on technical ideas and promotes skill development of team work.
- Interacts with peers across projects to secure resources and commitments.
- Handles frequent inter-organizational and outside customer contacts. Represents the organization in providing solutions to difficult technical issues associated with specific projects.
- Follows technical specification requirements and provides feedback on various technical processes and procedures.
- Presents effectively complex technical information/analysis and responds to questions from technical staff members and management.
- Works cooperatively and effectively within a team environment to achieve common goals and results, often influencing the outcome of the team(s).

OTHER DUTIES AND RESPONSIBILITIES

- Work direction responsibility may include technicians and junior engineers.
- May work with manufacturing and other functional groups on manufacturing and regulatory compliance issues.

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.
- Bachelor of Science Degree in Engineering, preferred.

Experience

- Minimum 4 years' experience.
- Two years of GMP manufacturing experience required.

Skills

- Requires demonstrated skills in technical innovation, technical leadership, mechanical and or chemical engineering, fluids engineering, and cellular biology.
- Strong interactive skills in general communication, cross-functional participation and influence, mentoring and acceptance of guidance, technical leadership, project management, coordination with cross-functional team member, team behavior, and support for subordinates, junior engineers, technicians, and management.
- Strong technical problem-solving skills.
- Mechanical and electronic ability aptitude to assist with equipment trouble-shooting.
- Understanding of and adherence to GMP practices and FDA regulations.
- Knowledge and ability to implement FDA or regulatory requirements as necessary.
- Demonstrated skill in direct communication and negotiation with certification agencies, including on-site agency audits and inspections.
- Demonstrated ability to communicate effectively both verbally and in writing.
- Knowledge and use of relevant PC software applications and skills to use them effectively.

-Or-

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

PHYSICAL REQUIREMENTS

General Labor Environment requirements include: use of personal protective equipment, reading, speaking, hearing, walking, bending, standing, stretching/reaching, hand/finger dexterity, and occasional lifting up to 50 pounds, or transporting up to 500 pounds via carts or mechanized equipment.

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.

Additional Physical Requirements

Requires travel based on business needs.

**Make plans to experience this year's 2019 RMPEX event first hand
on Friday, May 10th** <http://rmpex.org/>



Hello,

Today we congratulate **The City of Fort Collins** for winning the Malcolm Baldrige National Quality Award! Not only is this a great achievement for them, but it is also an exciting milestone for RMPEX. The Rocky Mountain region is home to many dynamic and highly performing organizations. The Commerce Secretary's announcement of the winners today underscores the quality of the organizations in our region. As a proud winner, The City of Fort Collins, joins a list of influential companies who have won the award, CH2M Hill OMI, Kenneth W. Monfort College of Business, Poudre Valley Health System, and Elevations Credit Union.

Bristol Tennessee Essential Services, Bristol, TN Stellar Solutions, Palo Alto, CA
(which also has Colorado operations) Castle Medical Center, Kailua, HI
Southcentral Foundation, Anchorage, AK

It takes many people, working together, to achieve these awards and in behalf of the Board of Directors and everyone connected with RMPEX I would like to thank the leadership of The City of Fort Collins, Dr. Jim Walker and the RMPEX team members who made this award possible.

Everyone who participates with the award process is enriched by the experience. We are grateful for the many volunteers who support RMPEX and performance excellence.

Best regards, Paul Brothe Executive Director

Rocky Mountain Performance Excellence (RMPEX), a 501C(3) organization serving as the regional organization for the Baldrige Performance Excellence Program, has named three organizations as 2017 recipients of performance excellence awards. One organization was recognized at the Peak level, the highest level award for RMPEX. Two organizations were recognized at the Timberline level for mature processes for the overall performance excellence requirements. Another organization received recognition at the High Plains level.

The next Quest Event will be at the Auraria Campus / Student Union in Denver in April 2019.
Check the RMPEX website starting in February of 2019.

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