

JANUARY CHAIR MESSAGE

I would like to welcome back my fellow ASQ chapter members to the Spring 2019 session. I hope you all had a Merry Christmas, Happy Hanukkah etc. and enjoyed the time off with your families, friends and loved ones. The New Year of course brings new resolutions, renewed optimism and change. Your Boulder ASQ Section is no different.

Beginning in January, several new Chairpersons will be serving you in new and different Section roles. Most notably Joe Wojniak will return to the Section Chairperson position for 2019-2020. Joe has been active in the Boulder ASQ Section for over 17 years. He has served as the Section Chairperson from 2012-2014 and is extremely capable and skilled Electrical Engineer; his skills will be extremely beneficial because ASQ National is reorganizing and flowing down new chapter requirements all the time. Joe is employed with Medtronic Brain Therapies - Neurosurgery as Sr. Quality Engineer in New Product Development in Louisville, CO. Joe has also served as the Boulder Section Vice Chair for 2016-2018.

Other notable section contributors include Dan Clark (LSS Black Belt) who will be filling both the Program and Education Chair roles. Dan has been serving the Boulder section since 1979. Gerry Naugle will contribute as Newsletter Co-Editor and has been serving the Boulder section since 1992. Arnold Miller will continue to contribute as Internet & On-Line Chair. Caroline Corwine will contribute as Section Treasurer. Bill Dunford will continue to contribute as Newsletter Co-Editor and assumed the role as Section Secretary. We welcome Albert Vergara as the new Vice Chair for 2019-2020.

We have interesting speakers and great tours set up for you in the Spring 2019 session. I look forward to seeing you at the January meeting.

Thank you,
Steve Reischel
ASQ 1313 Nominating Chair

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

Boulder-Area LSSBB Class Development

To all Lean Six Sigma Black Belts –

We are looking for certified Lean Six Sigma Black Belts within our section to help develop a “what should I do to become a LSSBB?” type of training.

The class will not be about learning the skills to pass the certification test (statistics, program management, etc.), but it should describe the path to become a certified LSSBB.

If you are interested in assisting the section with the content of this class, please contact Dan Clark, at 720-326-8240 (or) at dpclar@live.com.

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

ASQ Section 1313		Boulder, CO	
Title: Section Chair Name: Joe Wojniak Phone: 970-619-9395 Joe.wojniak@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		
Title: Financial Auditing Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Past Chair Name: Steve Reischel Phone: 720-890-2358 sreischel@yahoo.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 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 Jan 24th

Presenter: Ron Sedlock, quality Catalyst (see page 8)

Topic: After Six Sigma: What's Next?

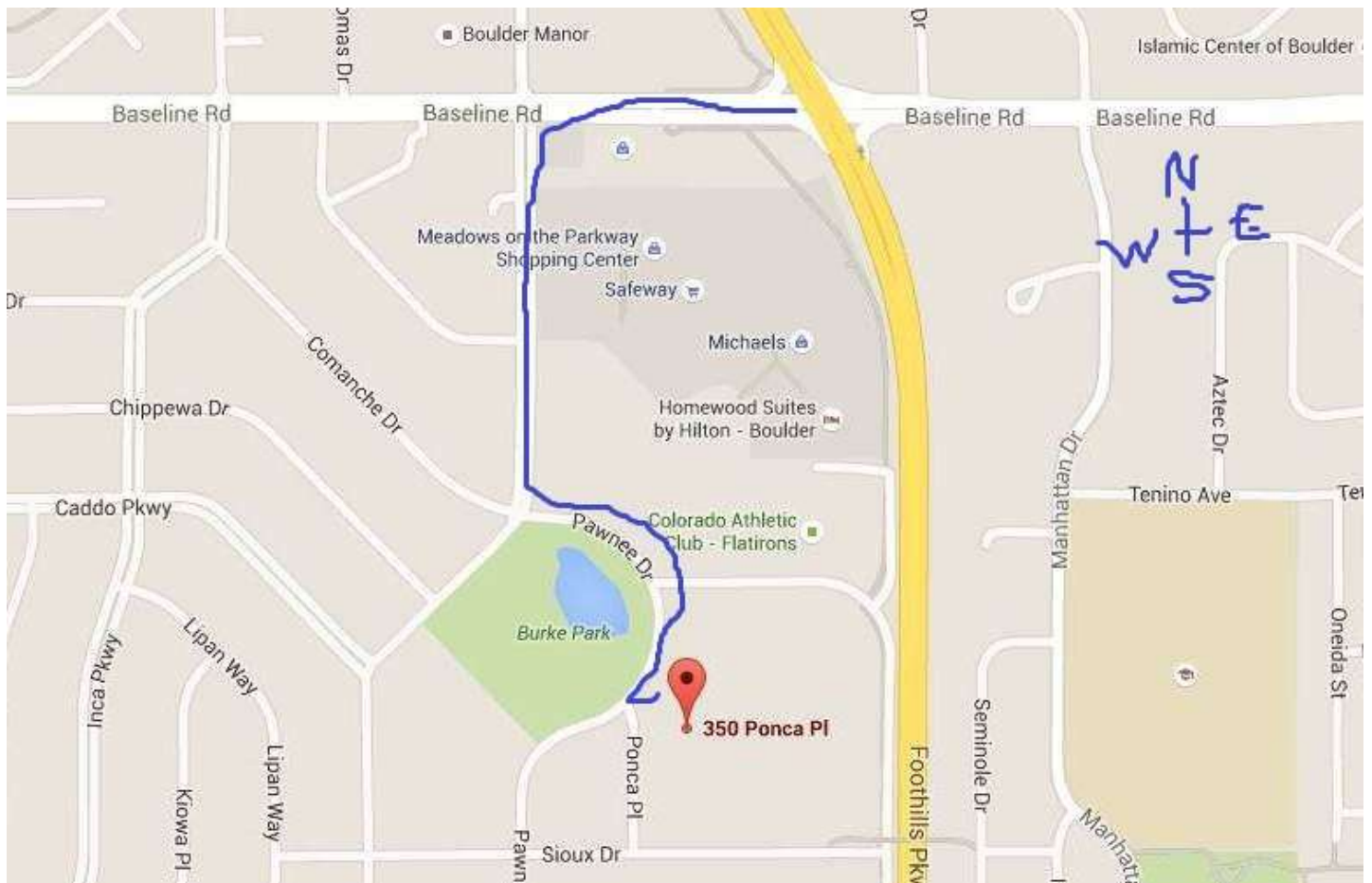
Abstract: During the presentation, Ron his will discuss current Six Sigma topics, and also about the value of ASQ certification. Added information and background on the career of Dr. W. Edwards Deming.

Ed note: This is a must-see.

Location: Frasier Meadows Healthcare 350 Ponca Place Boulder, CO 80303 in the North Community Room (located at the north-west end of the ground-floor hallway)

Doors Open at 5:30pm, Meeting Start Time: 6:00pm Meeting over ~7:45pm

Frasier Meadows Healthcare is located at the **Red !** on the map, below. The street going south from Baseline Road is **Mohawk Drive, and turn left (cont 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, as it is a huge building on the east side of the street. Please go in the main doors and sign into the building at the book on a small desk just inside the doors. Veer to the 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 (NW) to the North Community Meeting room where we will have the 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.



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.



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t: 414-272-8575
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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 website interface. On the left, under the heading "WHAT DO YOU WANT TO DO?", there are three main sections: "BUILD MY EXPERTISE" (with a sub-heading "MEMBERSHIP"), "DEVELOP MY ORGANIZATION" (with a sub-heading "REGISTRATION"), and "RECRUIT A NEW ASQ MEMBER AND EARN ASQ BUCKS.". The "BUILD MY EXPERTISE" section includes "LEARN" (with links for Training, Learn About Quality, ASQ TV, and Why ASQ), "CERTIFY" (with a link for Certifications), and "CONNECT" (with links for Communities, Career Center, Ask a Librarian, Blogs, and Get Involved). The "DEVELOP MY ORGANIZATION" section includes "Quality Resources" (with links for Books & Standards, Quality Progress, and Emerging Quality Leaders Program) and "Guides to Certification (PDF)". The "RECRUIT A NEW ASQ MEMBER AND EARN ASQ BUCKS." section has a "LEARN MORE" button. Below this, there is a "Download the Member Gift" section with a "LEARN MORE" button. The background of the right side shows a person's hands typing on a laptop keyboard.

Check out Quality Blogs on ASQ

<http://asq.org/blog/>

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.

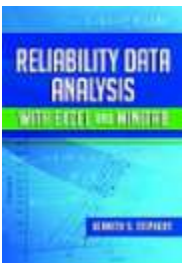


Bestseller!

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 10Jan2019

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	March 1 - 17, 2019	Feb 1, 2019	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631	\$400 members / \$450 others	April 5 - 21, 2019	Mar 8, 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.

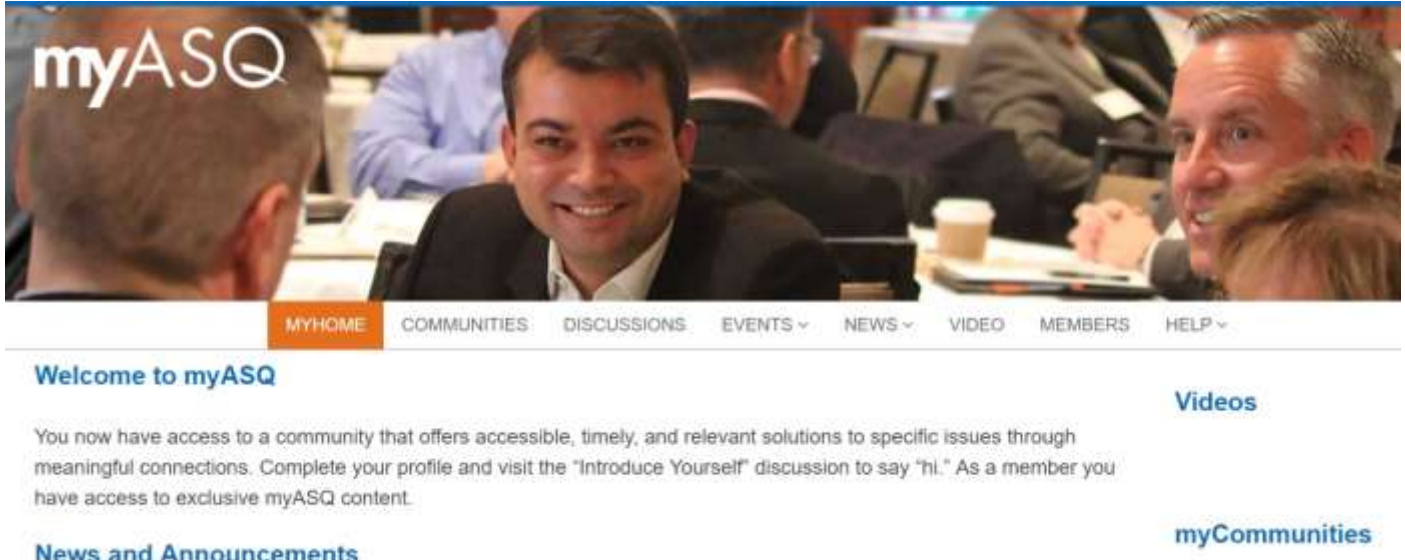
ISO 9001:2015 Transition Training: The first step in addressing ISO 9001:2015 and upgrading your certification is a comprehensive review of the standard. Cavendish Scott, Inc., is presenting a one day intensive workshop to do just that. You will understand the requirements of the standard, their application, 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

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.



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/>



Regulatory Affairs Project Manager

Req#: 18000MHH

Careers That Change Lives

As a Regulatory Affairs (RA) Project Manager, you will be a member of the Medtronic Respiratory and Monitoring Regulatory Affairs team, working directly with leadership, managers, and individual contributors to plan and execute projects to ensure our devices maintain compliance with changing regulations on a global scale. The focus of this role is to identify the emerging regulatory issues relevant to our product portfolio, analyze the broad scope of implications to the business, and implement long-term solutions to ensure market access is maintained according to the business strategy. This position will oversee these regulatory compliance activities for the Patient Monitoring (PM) and Respiratory Interventions (RI) portfolio within the Minimally Invasive Therapies Group (MITG) of Medtronic. As a leader of regulatory compliance, you will be expected to command influence throughout multiple global facilities and be generally recognized as the expert within the department on managing state of the art product compliance.

A Day in the Life / Responsibilities

- Manage a matrix of programs with well-defined plans and flexible deliverable methodologies to integrate new and changing device regulations enabling product regulatory compliance.
- Establish and effectively communicate program objectives in line the broader MDT strategy.
- Define project resource requirements and negotiate team assignments with functional managers, as required.
- Create and manage project plans, strategies, timelines and budgets to track progress and hold assigned resources accountable.
- Leverage the policies and procedures of the quality system to direct execution of program activities.
- Interface with a variety of management levels and subject matter experts to drive decisions on significant matters, often requiring the coordination of activity across functional groups.
- Maintain oversight of project risks and mitigation plans to ensure business and project objectives are met.
- Challenge teams to meet and exceed project goals and commitments.
- Provide routine project status communications to senior leadership.
- Solve issues through information exchange, influence and active persuasion to gain cooperation of other functions on program objectives.
- Lead in the understanding and awareness of global regulatory requirements to ensure compliance. Disseminate and provide guidance and continuing education, as applicable.

Must Have: Minimum Requirements

- Bachelor's Degree in Business, Engineering, or a technical discipline
- 5+ years of medical device and work experience in regulatory affairs and/or quality assurance with a Bachelor's Degree; or 3+ years of experience with an advanced degree.
- 1+ years of cross-functional project management experience.

Specialized Knowledge Required

- In depth knowledge of regulations and standards affecting the medical device industry.
- Experience with Project Management principles, concepts, practices and standards.
- Experience providing work direction, coaching and guidance to project teams.
- Experience with MS Office, including MS Project.

Preferred Qualifications

- Advanced degree preferred.
- Demonstrated competencies in project management resulting in measurable outputs.
- Experience with 510(k) applications, IDEs, PMA or PMA supplements and US device regulations and/or experience with other international medical device regulations and submissions.
- Experience with EU Medical Device Directive (MDD) 93/42/EEC and exposure to EU Medical Device Regulation (MDR) 2017/245 and industry standards.
- Experience with Corrective and Preventive Action processes and programs.
- Proven success working and negotiating with people from various disciplines, organizations, and cultures.
- Ability to follow scientific arguments, identify regulatory scientific data needs, solve regulatory issues, and define regulatory strategy.
- Strong attention to detail.
- Ability to work in a highly matrixed and geographically diverse business environment.
- Strong verbal and written communications with ability to effectively communicate at multiple levels in the organization.
- Ability to work independently with limited oversight.
- Ability to identify and solve problems in a strategic manner and to manage complex projects.
- Demonstrated ability to understand regulatory requirements and incorporate into business decisions.
- Confident and assertive style, goal oriented, and respectful of others.
- Team oriented and able to adjust leadership style to maximize effectiveness.

Physical Job Requirements

- The physical demands described within the Responsibilities section of this job description are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- While performing the duties of this job, the employee is regularly required to be independently mobile.
- The employee is also required to use a computer, and to communicate with peers and co-workers.

Make plans to experience next year's 2019 RMPEX event first hand.



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.

Rocky Mountain Performance Excellence ■ P.O. Box 17545 Denver, CO 80217 ■ 303-893-2739
<http://rmpex.org/>