

## MAY CHAIR MESSAGE

In my role as a Sr. Quality Engineer my time is spent on design remediation, working CAPAs or investigating why defined Quality Management System processes were not performed in the first place.

I have found over the years there are usually very good reasons to all of these issues. Sometimes those decisions are made by other departments in the organization; which brings me to my point. At the immediate past ASQ World Conference one of the presentations will be “Quality is Everyone’s Business”.

The trailer makes the point that an organization must have a culture of quality to be truly successful. I could not agree more. The question is, how do we as quality professionals effectively change the culture of quality in our respective organizations? For those who presenting or who attended ASQ World Conference, *if* the “Quality is Everyone’s Business” is first-class, I would ask you to provide me with feedback.

The subject of culture of quality is an issue all organizations face and could potentially be a valuable section presentation in the future. We know many of the attributes of an organization with a culture of quality, one of which is everyone in the organization has to be involved and know how their work affects quality. The same holds true for Boulder ASQ 1313.

I would encourage you to get involved because your participation is critical to having an active and vibrant ASQ section.

Thank you,

Steve Reischel  
ASQ Boulder Section Chair

**ASQ's Members and Customers Service Center:**

**E-MAIL:** [help@asq.org](mailto:help@asq.org)

**PHONE:** 800-248-1946

**FAX:** 414-272-1734

**USPS ASQ Communications**

**MAIL:** 600 N. Plankinton Ave.

**P.O. Box 3005**

**Milwaukee, WI 53201-3005**

*We suggest that you go to the ASQ National website at: [www.asq.org](http://www.asq.org) for complete ASQ national news, regional event(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** *The new job center below is in the updated ASQ National website.*

## WORK IN QUALITY

To continue helping our individual members and organizations thrive professionally, the new Career Center also has tools, tips, and services that can streamline the process of finding the perfect job or finding the ideal candidate.

### Job Seekers

[Find a quality job in the Career Center](#) Access all of the resources you need to find a job, post your résumé for employers to see, and manage your career for the long term.

### Employers

[Post a job in the Career Center](#) Post available jobs, find qualified candidates, and access statistics and other resources to manage the entire recruitment process.

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

## ASQ #1313 Officers & Committee Chairs 2018

ASQ Section 1313		Boulder, CO	
<b>Title: Section Chair</b> Name: Steve Reischel Phone: 720-890-2358 <a href="mailto:sreischel@yahoo.com">sreischel@yahoo.com</a>	<b>Title: Vice Chair</b> Name: Joe Wojniak Phone: 970-619-9395 <a href="mailto:Joe.wojniak@gmail.com">Joe.wojniak@gmail.com</a>		
<b>Title: Secretary</b> Name: Mark Norby Phone: 303-884-4783 <a href="mailto:mnorby@indra.com">mnorby@indra.com</a>	<b>Title: Treasurer</b> Name: Caroline Corwine Co-Chair Phone: 303-200-0068 <a href="mailto:carolinecorwine@yahoo.com">carolinecorwine@yahoo.com</a>		
<b>Title: Re-Certification</b> Name: Gerry Naugle Phone: 303-591-2830 <a href="mailto:gnaugle@earthlink.net">gnaugle@earthlink.net</a>	<b>Title: Internet &amp; Website</b> Name: Arnold Miller Phone: 303-466-2631 <a href="mailto:arnold.miller0@gmail.com">arnold.miller0@gmail.com</a>		
<b>Title: Publicity and VOC</b> Name: Byron Murray <a href="mailto:byron.murray@yahoo.com">byron.murray@yahoo.com</a>	<b>Title: Education Chair</b> Name: Dan Clark Phone: 720-326-8240 <a href="mailto:dpclark@live.com">dpclark@live.com</a>		
<b>Title: Financial Auditing</b> Name: Gerry Naugle Phone: 303-591-2830 <a href="mailto:gnaugle@earthlink.net">gnaugle@earthlink.net</a>	<b>Title: Past Chair</b> Name: Dan Clark Phone: 720-326-8240 <a href="mailto:dpclark@live.com">dpclark@live.com</a>		
<b>Title: Newsletter Co-Editor</b> Name: Gerry Naugle Phone: 303-591-2830 <a href="mailto:gnaugle@earthlink.net">gnaugle@earthlink.net</a>	<b>Title: Newsletter Co-Editor</b> Name: Bill Dunford Phone 720-340-0454 <a href="mailto:billdunford@hotmail.com">billdunford@hotmail.com</a>		
<b>Title: Certification</b> Name: Nixion Mead Phone: 720-320-6395 <a href="mailto:nixionmead@g.com">nixionmead@g.com</a>	<b>Title: Program Chair</b> Name: Beth Coody Phone 720-530-6276 <a href="mailto:bc@cscave.com">bc@cscave.com</a>		

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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 May 24th

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

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

## **Title -- Lean: Driving Impact for Citizens from Colorado State Government!**

"Improvement" and "Government" are not always seen as natural allies. In Colorado State government, we are working to change that! Come to our session on Thursday evening, May 24, and learn more! Outline of what we will cover:

1. Overview of Lean in Colorado State Government:
  - Importance (the need, the environment, dynamics)
  - Scale and impact
  - Challenges of Lean in the public sector CDOT's Deployment of Improvement and Innovation
2. CDOT's Deployment of Lean Improvement and Innovation
  - Structure and resources
  - Innovative methods (including Lean everyday ideas and the integration of change management)
3. Colorado's "SOLVE" Problem-solving Approach
  - Approach and toolkit
  - Case study (call centers; inspections) that highlights the tailored applicati
  - A quick exercise/tool

**Gary Vansuch** is Director of Process Improvement for the Colorado Department of Transportation (also known as "CDOT"). He directs efforts to improve the organization's operations, focused on making government more effective, efficient and elegant. He has over 30 years of business improvement and change leadership experience in the energy, financial services, research and governmental services sectors. Gary is a Lean Six Sigma Master Black Belt and a Certified Change Management Practitioner. Additionally, Gary served 6 years with the Malcolm Baldrige National Quality Award program, including 4 years as a Senior Examiner and as a member of the national Case Study Development Team. He has also been a Judge for the International Team Excellence Awards, and a Judge for the RIT / USA Quality Cup competition for improvement teams. CDOT's process improvement initiative has received national recognition, including designation as a "Bright Idea in Government" from the Innovations in American Government Awards program, which is administered by the Kennedy School of Government at Harvard University; and, as a winner of the 2017 North American Employee Engagement Award.

Frasier Meadows is where the **Red A** in the map below. Go in the main doors, and please sign into the building at 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 North Community Meeting room where we will have our ASQ Meetings. In this map, the street going south from Baseline Road is Mohawk Drive, and turn left onto 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, and it is on the east side of the street.



## 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.

## Updates to ASQ Re-cert Journal & Cost-Increase for 2018

Note: You can now re-certify on-line at the [www.asq.org](http://www.asq.org) website. There are 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 each three years remains the same. The new journal can be downloaded and printed directly from the main ASQ National website at: [www.asq.org](http://www.asq.org) using “Certification” / then the / Re-certification Link” or call ASQ Customer Care at: 1-800-248-1946 and request item B0525

The re-certification costs have recently increased due to higher costs to administer the program. Recertification by journal for members is now **\$69 for one certification** (or) **\$89 for two or more certifications** (e.g., if you get re-certified for two, three or more areas, you still only pay \$89).

**Anyone starting a re-certification journal through ASQ Boulder Section is strongly urged to send an e-mail before you start to the Re-cert Chair, Gerry Naugle, at: [gnaugle@earthlink.net](mailto:gnaugle@earthlink.net).**

**Deployed and effectively-implemented information which can save you time and expense.**

## Boulder Section's Current ASQ Fellows

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

Edward Arling  
Quality Compliance Assoc.  
(303) 579-9443  
[edward.arling@gmail.com](mailto:edward.arling@gmail.com)

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

## **Advertise in the ASQ Boulder Section e-newsletter in 2018-19!**

*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>
<b>One Issue (month)</b>	<b>\$20</b>	<b>\$30</b>
<b>Eight Issues (year)</b>	<b>\$50</b>	<b>\$80</b>

Interested? Contact Gerry Naugle at: [gnaugle@earthlink.net](mailto: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>

[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.

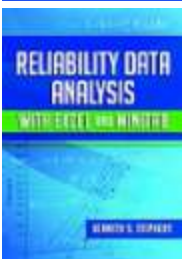


**Bestseller!**

**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.

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## 2018 ASQ Boulder Section Course Offerings

Updated 10May2018

Course Name	Instructor	Course Fee <sup>(1)</sup> <sup>(2)</sup>	Testing Window <sup>(3)</sup>	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	Aug 4 - 20, 2018	June 10 <sup>th</sup> 2018	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631	\$400 members / \$450 others	Aug 4 - 20, 2018	June 10 <sup>th</sup> , 2018	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>

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## **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 Gerry Naugle 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).

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

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### 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](mailto: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**

## **2018 Quality System Regulation Course**

Friday, June 15, 2018

8:00 am – 5:00 pm

First created by RMRAS in 1997, this is the must-attend course for all personnel working in quality systems or regulatory affairs in the medical device industry.

The Quality System Regulation Course is designed to provide students with a clear understanding of the requirements of this regulation as well as the deliverables that the FDA expects to find during their inspections.

[This year we are streamlining the program to focus on the most important parts of the regulation – CAPA, Complaint Handling, Non-Conformance, Validation, plus a few others](#)

### **Who should attend?**

This course is directed towards those who are responsible for the design, implementation and maintenance of the quality system; QA, R&D, manufacturing, and regulatory affairs. Management at all levels of the organization, especially those with executive responsibility, will find the legal and regulatory requirements and consequences covered in this course, enlightening.

### **Cost:**

Cost for the course is \$395.00 including all course materials, QSR booklet, continental breakfast and lunch.

### **Location:**

PPA Event Center, 2105 Decatur Street, Denver, CO 80211 *[immediately north of Sports Authority Field]*

### **Faculty**

#### **Ashleigh Wodushek, Global Process Owner – Quality Governance, Terumo BCT**

Ashleigh Wodushek has been in Colorado for the past 6 years and prior to that was in Portland, OR. She has her undergraduate degree in Biology and Chemistry and a Masters' Degree from Colorado State University. She started her career as an Investigator with the Food and Drug Administration in the Seattle District and later moved to the Denver District. During her time with the FDA she focused on Medical Devices and conducted inspections both domestically and internationally. Ashleigh was with the FDA about 7 years before joining Terumo BCT as a Quality System Compliance Auditor where she focused on supplier audits. Now she is the Global Process owner for Quality Governance and is responsible for the Global Audit process, Global Training and Personal process, and the Global Management Responsibility process.

#### **Amanda Zorn, Program Manager, Senior Compliance Auditor, Philips**

Amanda Zorn has been in the Medical Device Industry for over 9 years. She started as an Investigator with the Food and Drug Administration in the Chicago District and later transferred to the Denver District. Amanda earned her Level II Investigator Certification and became the Medical Device Specialist in the Denver District. Amanda is currently employed by Philips as the Program Manager for the Level 2 Corporate Audit Team as well as a Senior Compliance Auditor. She has also earned her ASQ certification for Quality Auditor and is ISO 13485 and 9001 Lead Auditor Certified.

**To register, please go to [www.regonline.com/2018QSR](http://www.regonline.com/2018QSR)**

For additional details or information, contact Nan Matthews, [programs@rmras.org](mailto:programs@rmras.org) or 303-843-6414.

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## **Quality-Related Career Openings / New Job Postings**

## Senior Regulatory Affairs Specialist

### Purpose:

Provide regulatory support for New Product, Sustaining Engineering, and/or Operations project teams by, identifying the appropriate domestic and international regulatory requirements and developing a regulatory strategy for global product commercialization. Ensuring product registrations are completed in accordance with project schedules. Assessing the domestic and/or international regulatory impact for process improvement and cost savings initiatives. Preparing and submitting documentation to domestic and/or international regulatory authorities, or overseeing this process for more junior level regulatory professionals. Communicating with regulatory agencies, as needed. Researching, preparing, and presenting information for global corporate audiences and senior management. Work independently without direct supervision. Performing other regulatory duties as assigned.

### Duties and Responsibilities:

- Represent the Regulatory organization in either cross functional design teams or ancillary support to develop and implement regulatory strategies and carry out associated output responsibilities.
- Prepare or supervise the preparation of global regulatory files/submissions for product registrations as assigned.
- Review and/or approve proposed design changes and ECOs to assess regulatory impact.
- Oversee documentation preparation on various projects, providing guidance and mentoring to junior level RA professionals.
- Assist in reporting and presentation compilation for senior management.
- Interfaces with other ConMed business units/affiliates/distributors as assigned.
- Perform other related duties and special projects as required by management.
- Prepare clinical evaluations.
- Manage product recalls.

### Work Experience Requirements:

- Minimum of five to seven years in a regulatory affairs position that includes proof of hands-on submission experience is required.

### Education Requirements:

- Bachelor of Science degree in a science, technical, or related field required or equivalent.

### Knowledge Requirements:

- Knowledge of domestic and international medical device standards and regulations. Knowledge of domestic and international labeling requirements. Ability to execute assignments independently as assigned., Must possess strong organizational skills. Must possess strong written and verbal communication skills. Must possess demonstrated ability to handle multiple priorities simultaneously. Proficient on Microsoft Office products. Multi-Lingual candidate preferred.

### How to apply:

- Please apply directly to our career page:  
<https://recruiting.adp.com/srccar/public/RTI.home?c=2166901&d=External&r=5000336788206>
  - You can also submit your resume to: [Loricolby@conmed.com](mailto:Loricolby@conmed.com)
-

## Benefits

*Be rewarded*

CONMED offers competitive compensation

Excellent healthcare including medical, dental, vision and prescription coverage

Short & long term disability plus life insurance – cost paid fully by CONMED

Retirement Savings Plan (401K) – company match dollar for dollar up to 7%

Employee stock purchase plan – allows stock purchases at discounted price

Tuition assistance for undergraduate and graduate level courses

## About CONMED

*Get in*

CONMED Corporation is a progressive, global medical device company. Through thoughtful leadership, innovation and team work, we are changing the future of medicine. Our 3,500 employees worldwide make meaningful contributions, positively impact the business, and advance in their careers as our company and product portfolio grows.

We are a leader in Orthopedics, General Surgery, Gynecology, Gastroenterology, Pulmonology, and Anesthesiology and our employees enjoy challenging and diverse job opportunities across these varied specializations. We are headquartered in upstate New York with additional domestic facilities in FL, CA, MA, NJ, CO, and GA. We have an international presence in more than 20 locations throughout Europe, Australia, Latin America, Asia, North America, and the Middle East.

*CONMED is an Equal Opportunity Employer & an Affirmative Action Employer. CONMED is a strong advocate of workforce diversity. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or veteran status.*

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

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**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://rmras.org/>

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Health innovation that matters

Help advance our goals to obtain and maintain medical device approvals globally.

Assist as necessary to obtain medical device market clearances in Europe and international markets as well as support submissions in the US and Canada. Ensure timely preparation of complete and accurate submission documentation. Maintain existing world-wide regulatory clearances, licenses and registrations.

Core activities include:

- Researching, generate and compile the documentation required to support worldwide medical device registration/licensing activities
- Creating and maintain EU technical file
- Responding to information requests to government agencies, distributors, customers and company personnel
- Supporting new product and product modification projects to assure regulatory compliance
- Organizing and maintain internal regulatory files
- Assuring compliance with company policies and procedures
- Assisting in the preparation of 510k and Health Canada submission packets for new products and product modifications

You must:

- Enjoy researching information, generating documentation and maintaining files.
- Have a good understanding of medical devices documentation requirements.
- Have solid writing and organizational skills.
- Be detail oriented and have strong reasoning skills.
- Be able to achieve goals with minimal direction and also follow specific instructions as necessary.
- Be flexible and willing to provide support as needed.
- Be able to maintain the confidentiality of sensitive information.

For this role, your experience should include at least 2 years working in Regulatory Affairs or 5 years working for a medical device manufacturer in an applicable role. A BA/BS University degree is required.

Our Cardiopulmonary Division designs manufacture and distributes devices for worldwide markets. As our Regulatory Specialist, your contributions will ultimately help further our commitment to improving the lives of our patients and their families worldwide!

Are you ready to make a difference? If so, please send your resume to:

**[scott.light@livanova.com](mailto:scott.light@livanova.com)**

The facility location is:  
14401 West 65<sup>th</sup> Way  
Arvada CO 80004

**Make plans to experience this year's 2018 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.**

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**The next Quest Event will be at the Auraria Campus / Student Union in Denver in April 2018.  
Check the RMPEX website starting in February of 2018.**

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