

MAY CHAIR MESSAGE

Being quality professionals in ASQ Boulder, we are responsible for a wide range of quality functions and tasks at our respective companies. Some of us ensure the Quality Management System meets applicable ISO 9001, 13485 or 14001 standards; others perform Management Review while others focus on new product introduction, statistical analysis and reliability. Regardless of which industry we work in, we might agree that most ISO certified companies spend a significant amount of effort on the Corrective Action & Preventative Action (CAPA) process. Although the CAPA process is well defined and documented, many companies struggle with the level of response, which is normally governed by risk vs doing too little and having to revisit a corrective action that proves to be ineffective.

I think it would be interesting to hear from the section on what CAPA strategies and quality tools work best in your respective industry and why. We have very skilled quality professionals in the Boulder section. This is an opportunity to share industry best practices, which could be “sticky” on the website for future reference. The April 2017 Quality Progress article, “How to Pitch Your Ideas to Others” may help me? Stay tuned.

The Program Committee would also like to hear from you about suggested tours and lectures going forward. We are working on finding more talks and tours that revolve around quality in the healthcare system. Since the icy weather limited the attendance of the Medtronic capital equipment tour in February, we are considering another Medtronic tour in the fall 2017. Please provide feedback to the Program Committee. Thanks for reading, Steve

The executive board wishes to thank John Beachman for his many years of service to the Boulder Section, and that he and his wife enjoy subsequent years in AZ, in most likely Phoenix or Tucson.

The section is seeking a member who knows bookkeeping principles and use of tabbed EXCEL type spreadsheet, and who would be interested in being the Section Treasurer. Estimated time is 20 minutes per month. You receive 1.5 RU's per year towards re-certification. If you are interested, please contact any present board member.

Next Boulder Section Meeting is on Thurs, May 25th at: Frasier Meadows Healthcare, 4th Floor Meeting Room. Doors open at 5:30pm. More meeting details and map on page 3. One brand-new May '17 Job posting, starting on page ten.

ASQ's Members and Customer Service Center:

E-MAIL: help@asq.org

PHONE: 800-248-1946

FAX: 414-272-1734

USPS ASQ Communications

MAIL: 600 N. Plankinton Ave.

P.O. Box 3005

Milwaukee, WI 53201-3005

We suggest that you go to the ASQ National website at: www.asq.org for complete ASQ national news, regional event(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



May Member Gift Bundle

We suggest that you log-in to the www.asq.org and in the member area Links, claim in there your May 2017 member gift bundle.

Lancaster Medal presented to Elizabeth M. Keim, Integrated Quality Resources LLC, Niwot, CO

“For the outstanding role model she has presented to the global fraternity of quality serving both as an exceptional professional coach, teacher, and goodwill ambassador for quality by promoting quality across five continents over the past ten years.”

Editor note: Liz Keim is a current Boulder Section member, a past Section Chair, past ASQ President & Board Chair and is an ASQ Fellow (see page 5)

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

ASQ Section 1313 Boulder, CO	
Title: Section Chair Name: Steve Reischel Phone: 720-890-2358 sreischel@yahoo.com	Title: Vice Chair Name: Joe Wojniak Phone: 970-619-9395 Joe.wojniak@gmail.com
Title: Secretary Name: Mark Norby Phone: 303-884-4783 mnorby@indra.com	Title: Treasurer Name: John Beachman Phone: 720-313-2746 Jlbeach303@gmail.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: Dan Clark Phone: 720-326-8240 dpclark@live.com
Title: Newsletter Co-Editor Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Newsletter Co-Editor Name: Bill Dunford Phone 720-340-0454 billdunford@hotmail.com
Title: Certification Name: Nixion Mead Phone: 720-320-6395 nixionmead@q.com	Title: Program Chair Name: Matt Leiphart Phone 303-243-2603 mattleiphart@gmail.com

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Lean & Six Sigma Blended Learning

Take Your Company Further

Whether you are starting or moving ahead with your **Lean Process Improvements**, our blended learning will be valuable to your improvement processes. Our eLearning courses will provide you with online modules that will blend with classroom instructor training. **Here are some benefits of our Blended Learning Options:**

24/7 email/phone assistance by one of our certified Master Black Belts Onsite training at any location
 Customized training for specific industries. With over 100 modules available, we can customize your course to meet your organization's specific needs including Lean modules that are available in Spanish. Here is a sample of some popular standard courses:

- Lean Essentials*
- Lean Essentials Healthcare*
- Lean Six Sigma Yellow Belt*
- Lean Six Sigma Green Belt*
- Lean Six Sigma Black Belt*
- Project Management*

Online
Blended Training

Lean and Six Sigma

**Lean Six Sigma Experts-LSSE 3609 Wadsworth Blvd. #380 Lakewood, CO 80235
 (800) 961-9479**

Upcoming May 2017 ASQ Boulder Section Meeting

Thurs, May 27th Place: **Frasier Meadows Healthcare, 4th Floor Assembly Room, Boulder, CO 80303**

Presentation topic: ASQ Recertification Time: **5:30pm to 7:45pm** Cost: **Free**

Request an RSVP on the [Section's "Meet-up Link" meeting](#)

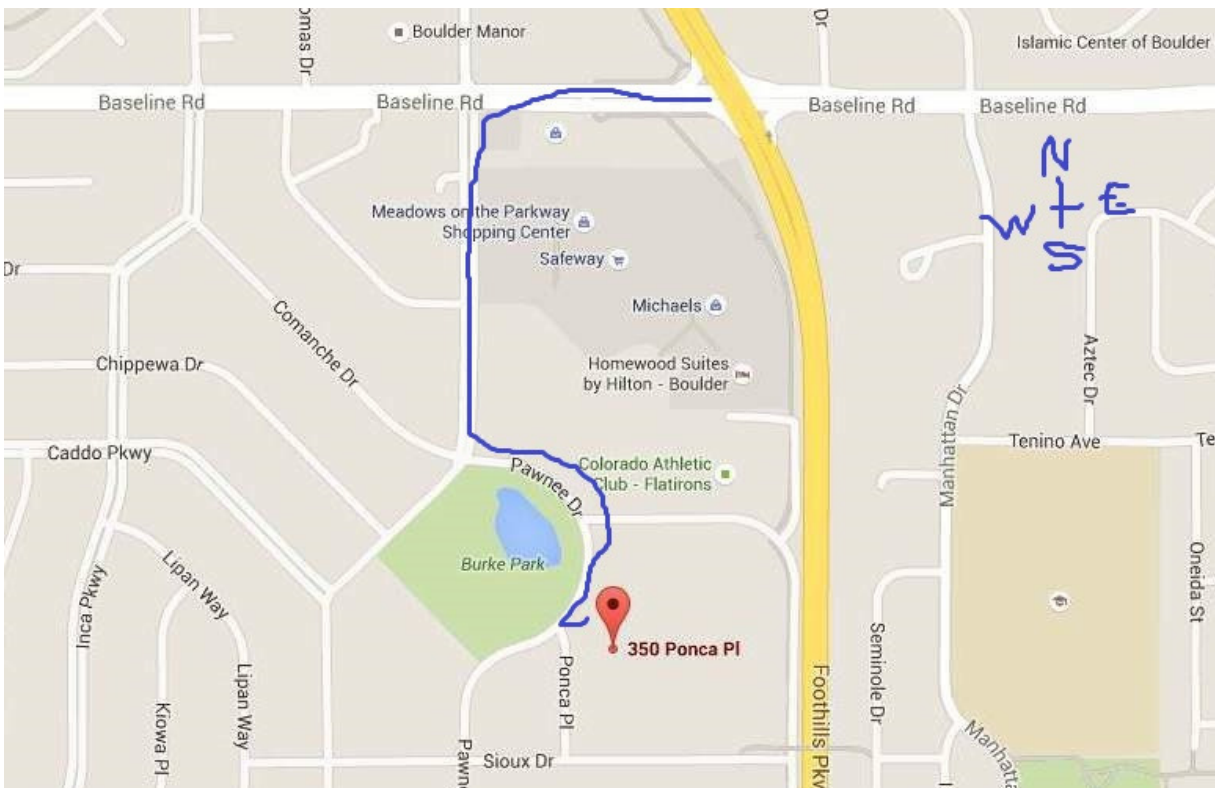
Abstract: If you're newly certified and you haven't gone through recertification, or if you'll be recertifying in 2017-2018+ this presentation introduces what's new. Can I still recertify by exam? Yes, but you don't have to! Many people opt to recertify by Journal- this presentation covers the basics of Journal recertification and the new option of submitting Journals online. We'll also log onto ASQ.org and navigate through the pages in a quick demo.

Speaker bio: Joe Wojniak has been a quality engineer for 15 years and has held the Certified Quality Engineer since 2007. Joe has recertified 3 times: 2010, 2013, 2016, and is due for re-cert in 2019! Joe has worked in several industries in Manufacturing Engineering, Quality Engineering, and New Product Introduction. For such companies as Flextronics, Covidien (now Medtronic Minimally Invasive Therapies Group), and Medtronic Surgical Navigation (Restorative Therapies Group).

Section re-cert Chair Gerry Naugle will be there also, to answer any additional questions on re-cert aspects and/or evidence(s).

*Frasier Meadows is where the **Red A** in the map below. Parking is ample to the south of the front main doors. 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 4th floor, and walk south in the hallway about 40 feet to the Assembly 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 not miss Frasier Meadows as it is about the same size as a pyramid.*



ASQ National – and – Local ASQ Section’s News

News continued from page 1

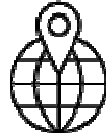
ASQ COMPUTER-BASED CERTIFICATION TESTING



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 2017

Note: You can now re-certify on-line at the 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 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.

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 2017-18!

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

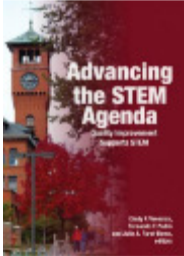
The section website for much information and resources' links' is: <http://asqBoulder.org>

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.

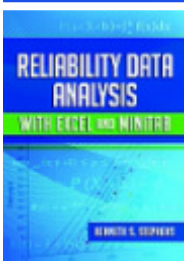


Bestseller!

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.

2017 ASQ Boulder Section Course Offerings

Updated 12 May 2017

Course Name	Instructor	Course Fee ⁽¹⁾ ⁽²⁾	Exam Date ⁽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	Aug 4-20, 2017	Jul 7, 2017	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631	\$400 members / \$450 others	Aug 4-20, 2017	Jul 7, 2017	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 dates associated with conventions. <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 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).

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 2016.

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 2016.

984 S Vine St, Denver, CO 80209

phone: (303) 480-0111

Quality-Related Career Openings / New Job Postings

Corgenix Corp

IDENTIFYING INFORMATION:

Job Title: Quality Assurance Associate
Department: Clinical, Quality and Regulatory Affairs
Reports to: Quality Assurance Supervisor

II. GENERAL PURPOSE:

Oversees Quality Assurance activities to ensure compliance with regulatory agencies, ISO and Corgenix requirements.

III. KEY RESPONSIBILITIES:

1. Review and final approval authority for Device History Records (DHR) and subsequent final product.
2. Oversee Purchasing Controls for critical A and B materials in accordance with the Approved Vendor list and regulatory requirements.
3. Manage the Approved Vendor List, additions and removals.
4. Final disposition authority for incoming materials, including packaging and labeling, used in product manufacturing. Responsible for in-process kit component inspections and final product inspections.
5. Perform Quality Assurance review of Nonconformance Reports and Planned Deviations assuring all internal and regulatory requirements are met.
6. Assist in establishing document approval and change control procedures. Assist with document control procedures, as necessary.
7. Final review and sign off approval for new documents/new document revisions prior to distribution.
8. Manage filing and database inputs of quality documents (e.g. NCR, PDN, RP, housekeeping records, Material Action Tickets, Action Impact Reviews, device history records).
9. Conduct and assist as needed with the Corgenix Internal Audit Program.
10. Maintain the Corgenix Training Program and assist with company awareness of the Corgenix Quality System and provide support and training on Quality issues.
11. Continually assess and improve Quality System Processes.
12. Other duties as assigned by Supervisor.

IV. PERSONAL CHARACTERISTICS:

The responsibility of this position is managing specialized work efficiently, with confidence and competence. The position requires above average attention to details, concern for the exact correctness of work, and strong commitment to tasks completed on time. The person in this position will take work seriously, has a strong sense of duty, and is disciplined. A somewhat faster-than-average pace will be the norm for this position. Detailed, specialized work is the major focus.

The position will generally be task oriented, requiring someone with a conservative, careful, and cautious approach to work.

V. CONTACTS:

INSIDE COMPANY: Works closely with Quality Control, Document Control, Manufacturing, Marketing, Regulatory Affairs, and R&D.

OUTSIDE COMPANY: Raw material suppliers concerning quality and compliance issues. Possible interaction with regulatory authorities, Quality System Registrars, or contract customer representatives.

VI. JOB TITLE DIRECTLY SUPERVISED:

N/A

VII. WORKING CONDITIONS

This position primarily functions in a typical office environment. Due to the interaction with Quality Control and Manufacturing, this position will occasionally function in a laboratory setting with risk of exposure to biological and chemical hazards associated with such a setting. The position requires a moderate level of mental exertion, with the individual having to respond to short deadlines and crises. The position may require in excess of forty hours per week and generate a moderate amount of stress.

VIII. SPECIALIZED EQUIPMENT USED:

General office equipment including personal computer hardware, standard computer software (e.g., word processing, spread sheets, database, statistical programs), copiers, Fax machines, paper shredder, paper binding equipment, and printers.

IX. ACCOUNTABILITY/SCOPE OF THE POSITION:

This position is accountable for the Quality Assurance activities of the company. It is a highly visible position, integral to the Company's short and long term success. This position is key to the long and short term success of the company and requires a high level of commitment to the goals set by the Quality and Regulatory Affairs Department and the company.

X. MINIMUM POSITION REQUIREMENTS:

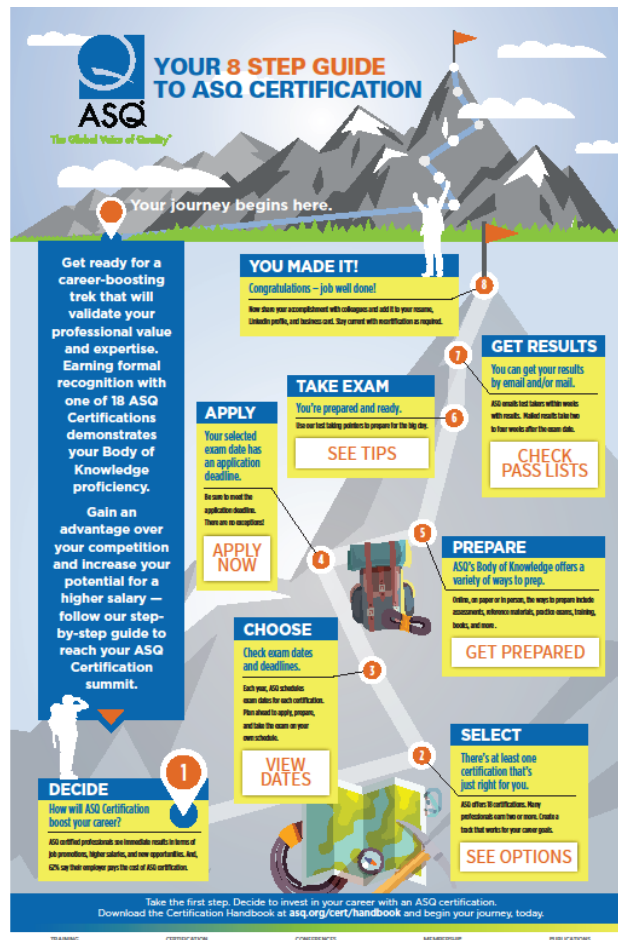
BACKGROUND KNOWLEDGE: A Bachelor's Degree in a science discipline, or relevant quality assurance experience. Working knowledge of Quality Assurance principles and methods is required.

EXPERIENCE: For degreed individuals, this position requires a minimum of 3 years working experience in a GMP/FDA regulated environment. For non-degreed individuals, the requirement is 6 years in a GMP/FDA regulated environment. Quality Assurance/ Regulatory Affairs experience is preferred.

GENERAL: This person must demonstrate the ability to work and think independently. A high level of attention to detail and strong initiative are required for this position.

XI. APPLICATION INSTRUCTIONS

Qualified candidates should submit resume/CV and cover letter to Malissa Sailakham, Quality Assurance Supervisor via email at msailakham@corgenix.com.



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.

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/>

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



Rocky Mountain Performance Excellence announces three Recipients of the 2017 Performance Excellence Awards and one Recipient of Recognition. These groups were honored at the "Quest Event" on April 14th, 2017 at the Auraria Campus / Student Union Building in downtown Denver.

[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 2017 RMPEX recipients are:

Peak Level

Denver Health, Denver, Colorado, an academic, community-based health care system that serves as Colorado's primary safety net organization. This is the second time Denver Health has been recognized with an RMPEX Peak Award.

Timberline Level

El Paso County School District 49, which serves the eastern part of Colorado Springs and the unincorporated portion of El Paso County known as Falcon.

Fire & Police Pension Association of Colorado (FPPA), Greenwood Village, Colorado which administers a statewide retirement system as well as death and disability coverage for police officers and paid firefighters throughout the State of Colorado.

High Plains Recognition

Office of Natural Resources Revenue (ONRR), Denver, Colorado, which manages and ensures full payment of revenues owed for the development of the Nation's energy and natural resources.

The next Quest Event will be at at the Auraria Campus / Student Union in Denver in 2018.
Check the RMPEX website in February of 2018. www.rmpe.org

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