

SEPTEMBER CHAIR MESSAGE

Welcome to the 2015-2016 season for ASQ. I hope you all had a wonderful, fun-filled summer. As the weather turns cooler and as we look forward to the aspen turning colors in the next few weeks, the ASQ section meetings will be resuming. Your committee has been hard at work developing a meeting and education program for the year. It is a work in progress but I believe you'll find it very interesting and educational – our plan is to maintain the alternating speaker/tour program as the year unfolds.

To kick off the year, I'd like to introduce myself. I am a degreed Engineer and a Lean Six Sigma Black Belt (I've been told by many that getting my LSS certification was much like getting a Master's degree – for those with Master's degrees, I have a newfound respect!). I have worked in the manufacturing field for more than 35 years as a Quality Engineer, Production Engineer, and Continuous Improvement Manager, among other things. During this time I was a paying member of ASQ and was involved with the local sections, in one form or another. It has only been the last several years that I got involved with the leadership portion of the section. Why? I felt it was time to give back to the section what I had gained from its members and I felt I could help improve it in a small way.

So why was I hesitant up until now? Time? Knowledge? Expertise? I'm not sure. When I finally joined the leadership ranks I found that we are all just folks with similar backgrounds and work interests trying to make our work lives better and feel ASQ has much to offer; ASQ wouldn't exist if it wasn't for its members. I also found that ASQ is also a great network if you are looking for new opportunities. Use it to your advantage!

The section is here for its members (that's you and me) and the leadership's role is to guide these efforts. I encourage you to get involved in the section, even if it means offering suggestions for direction and improvement. Feel free to reach out to any of the committee or members if you have any questions, concerns, or opportunities for improvement. Remember, we are all in this together.
Yours in service, Dan Clark

We'll have a Dec "Spouses Night" again at the Boulder Dinner Theater on Wed, Dec 16th. There will be 18 seats available on a "first come, first reserve and first pay basis per couple". Details the same as previous years with 50% ticket subsidy from Section. Show is the Musical Comedy of the Addams Family. You can put in a RSVP as "a place holder", effective now. One of the two in your party must be a paid-up ASQ and a Boulder Section Member. Contact Gerry Naugle (info on page 2) to make a RSVP.

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, including member upgrades and what 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



Keep Calm and Prepare for ISO 9001:2015

Revisions of ISO management systems are often accompanied by a bit of anxiety. More than 1 million organizations have been certified to ISO 9001:2008, the international quality management system (QMS) standard, and they now must embark on implementing a revised version to be published later. What are the key changes we must be aware of? When and how should we introduce the required changes? What resources will we need? Check at ASQ website, at: www.asq.org

ASQ National and Boulder Section News is continued on page 4
ASQ #1313 Officers & Committee Chairs 2015-16

ASQ Section 1313		Boulder, CO	
Title: Chair Name: Dan Clark Phone: 720-326-8240 dpclark@live.com	Title: Vice Chair Name: Arta Doci Phone: 720-256-6677 Arta.doci@gmail.com		
Title: Secretary Name: Patricia Fleenor Phone: 303-501-8457 patricia.fleenor@zimmrbiomet.com	Title: Treasurer Name: John Beachman Phone: 720-313-2746 Jibeach303@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: Joe Wojniak Phone: 970-619-9395 Joe.wojniak@gmail.com		
Title: Financial Auditing Name: Ewald Schelert Phone: 303-702-9009 schelert@mesanetworks.net	Title: Past Chair Name: Joe Wojniak Phone: 970-619-9395 Joe.wojniak@gmail.com		
Title: Newsletter Co-Editor Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Newsletter Co-Editor Name: Bill Dunford Phone: 720-340-0454 billdunford@hotmail.com		
Title: Certification Name: Nixon Mead Phone: 720-320-6395 nixonmead@q.com			

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Online Content Exclusively for Members:

Member Gift Bundles: Check at the ASQ Website September 2015 Member Gift Bundle – A Beginner’s Guide to Quality

- Learn About Quality
- The History of Quality
- Total Quality Management - Webcast
- Root Cause Analysis – Articles and Webcasts
- Basic Quality Tools – Webinar Series
- PDCA
- Quality Improvement Made Simple...and *Fast!* – eBook

Download your gift today



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



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

Upcoming September ASQ Boulder Section Meeting

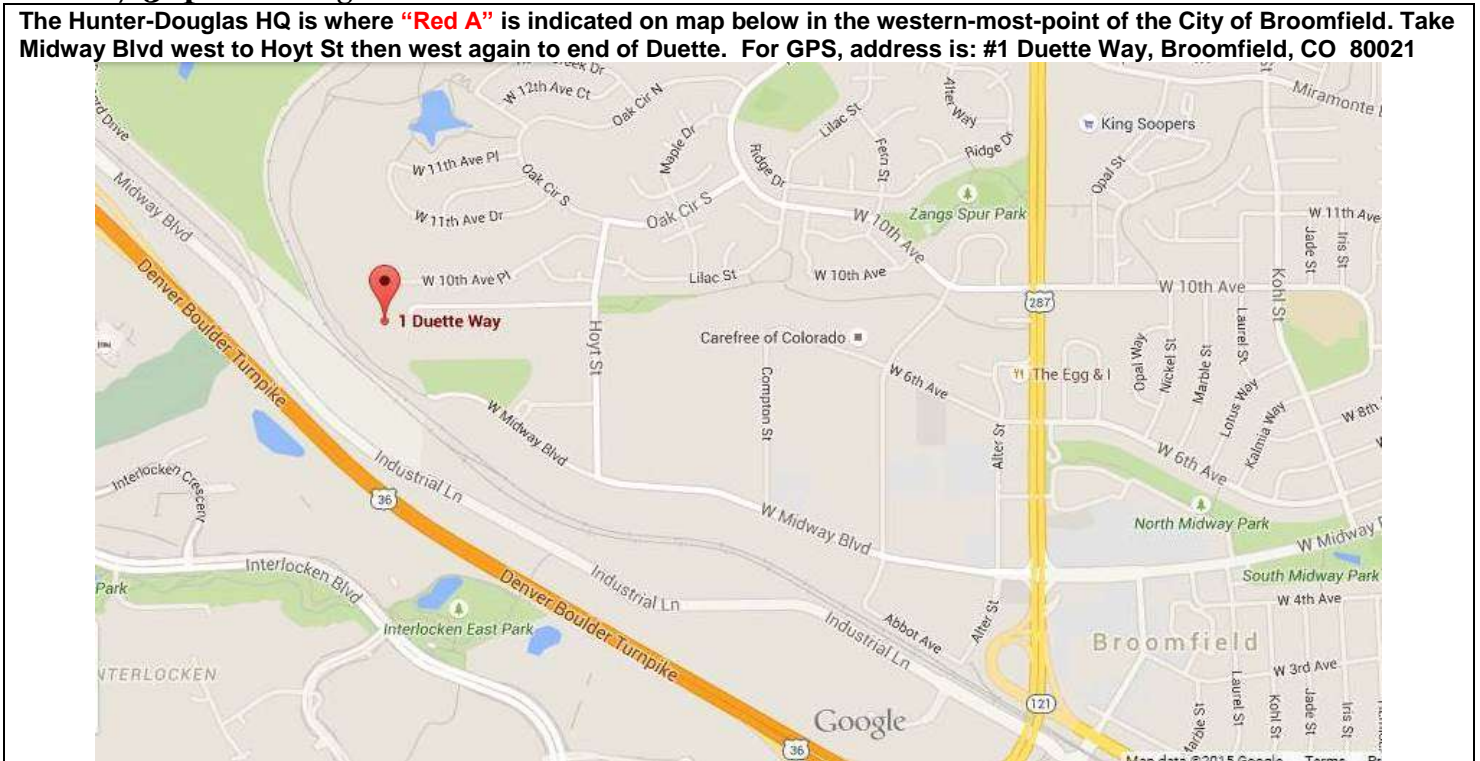
Sept 24th Meeting at the Hunter-Douglas HQ Building, #1 Duette Way, Broomfield in 3rd Floor Conference Room

5:15pm We suggest to arrive 15 minutes early to sign-in **5:30pm** Snack-Food and Networking

6:05pm Welcome to section and announcements **6:15pm** Presentation

- **Speaker:** Ms. Genevieve Cavallo, Business Analyst II, Elevations Credit Union in Boulder
- **Topic:** Overview of how the credit union planned and developed, ran for, and earned the Malcolm Baldrige National Quality Award [a joint NIST & ASQ National Program] in 2014 for “Services Sector”
- **7:30pm** meeting over

The Hunter-Douglas HQ is where “Red A” is indicated on map below in the western-most-point of the City of Broomfield. Take Midway Blvd west to Hoyt St then west again to end of Duette. For GPS, address is: #1 Duette Way, Broomfield, CO 80021



RMPEX Rocky Mountain Performance Excellence Program (which is also the Colorado State Quality and Business Performance Program), please see articles starting on [page 12](#) for most recent information of RMPEX activities and events. The Boulder ASQ Section is an active sponsor of the RMPEX Organization. <http://rmpex.org/>

RMRAS Rocky Mountain Regulatory Affairs Society <http://rmmas.org/> RMRAS is the premier local professional society in the Denver-front range area for individuals involved in medical devices or the pharmaceutical industries. Membership is free of charge. And, our societies’ recertification units (RUs) are reciprocal and interchangeable.

News continued from page 1

ASQ National – and – Local ASQ Sections’ News

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>

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

Updates to ASQ Re-cert Journal & Cost-Increase for 2015

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. *Abstract: there are deployed and effectively implemented policies & procedures which can save you some time, effort and USPS postage.*

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 2015-16!

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

<u>Number of Issues</u>	<u>¼ Page</u>	<u>½ Page</u>
One Issue (month)	\$20	\$30
Eight Issues (year)	\$60	\$80

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

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.

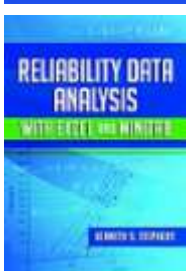


Bestseller!

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, Joe Wojniak, (970) 619-9395 to see if the class you want can be made available in the Denver-North Loveland or Ft. Collins area.

2015 ASQ Boulder Section Course Offerings

Updated 09-07-2015

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 Location: Contact Instructor	\$400 members / \$450 others	10/3/2015 3/5/2016	Past Deadline 1/15/2016	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631 Location: TBD	\$400 members / \$450 others	10/3/2015 3/5/2016	Past Deadline 1/15/2016	TBD	TBD
1322 - ASQ Exam BoK: Quality Concepts, Management and Leadership	Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD	\$270 per student + \$25 material = \$295 Total	10/3/2015 3/5/2016	Past Deadline 1/15/2016	TBD	TBD
1323 - ASQ Exam BoK: Statistical Principles, Techniques and Applications	Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD	\$270 per student + \$25 material = \$295 Total	10/3/2015 3/5/2016	Past Deadline 1/15/2016	TBD	TBD
1324 - ASQ CQE Book of Knowledge (Bok) Review	Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD	\$135 per student + \$15 material = \$150 Total	10/3/2015 3/5/2016	Past Deadline 1/15/2016	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, Joe Wojniak (970) 619-9395 <http://asqBoulder.org> courses If there is a class you need but is not listed above. We may be able to offer that class in the future.

COURSE REGISTRATION INFORMATION

You do not have to be a member of ASQ to attend a class however, members of ASQ and other professional societies receive a discount for classes. Local Quality professionals teach all classes in the Boulder/Longmont /Broomfield area unless otherwise noted. We contact you at least two weeks in advance of the class start date for the exact location. Classes are typically held at a company that employs one of the students. You may nominate your company for hosting a class. Directions and registration confirmations are provided. Participants receive a certificate upon completion of the course. We need a minimum of about 4 - 5 students to hold a course and we reserve the right to cancel or postpone classes not having enough students. A full refund will be given if minimum class registration requirements are not met. If you cancel within two weeks prior to a class beginning you may not receive a refund.

ASQ CERTIFICATION REVIEW COURSES: These courses are intended as a refresher course for those preparing to take the ASQ Certification exam. These courses are typically not introductory and are intended for people with either academic and/or on the job experience. NOTE: Enrollment in a class DOES NOT enroll the student for the certification exam. The student is responsible for confirming exam dates and application deadlines with ASQ Headquarters. Qualification requirements for sitting for an exam and information regarding exam applications may be obtained by calling ASQ Headquarters at 1-800-248-1946 or go to <http://www.asq.org>

ASQ #1313 COURSE REGISTRATION FORM

Please complete the following information as thoroughly as possible. In case of a schedule change or cancellation, we really appreciate two phone numbers to contact you.

Student's Name: _____ ASQ Membership #: _____
or other Society and #: _____

Title of Course: _____

Company Name: _____

Address: _____

Daytime phone: _____ Night time phone: _____

E-Mail: _____ or FAX: _____

Course # and Name: _____

Course Start Date: _____

Course Fee: \$ _____ (ASQ Member) \$ _____ (Non-member)

Please enclose a check payable to "**ASQ Boulder Section**" and contact the Boulder Section Education Chair Joe Wojniak, (information on page 2) to reserve your spot in the course that you want.

Please send checks to this address:

ASQ Section 1313 Education c/o Gerry Naugle, P.O. Box 3783 Boulder, CO 80307

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

Hard to believe but it's the second half of 2015. Although my availability is somewhat limited for the rest of the year, let me know if you have any training needs. If you are seeking ASQ certifications I do exam preparation classes for most certifications. For the December exams such as:

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

You should begin the exam preparation process no later than September. Also the following are a couple of my most popular courses:

- **Statistics: Principles and Applications**
- **Process-based Audits (ISO9001:2015)**

In these tough economic times, I have given and will continue to give individuals advice on quality and exam preparation. This is a free service. Let me know how I can help.

Ron Sedlock the quality Catalyst phone: 303.587.9153 www.thequalitycatalyst.com

I am vitally concerned with your privacy on the internet and respect your right to refuse any other email distributions from me. I do limit my email announcements to typically 2 times a year. If you choose to discontinue these mailings, let me know. Your email address will be immediately removed from my database.

Colorado Quality Executive Network (CQEN)

This is a network of the top quality executive from various Colorado organizations. The purpose of CQEN is to share ideas on current quality trends and issues. Membership to the CQEN is by invitation only, however please contact us to join.

Date: October 15th, 2015 Time: 1:00 to 5:00 pm

Location: Hunter-Douglas HQ #1 Duette Way, Broomfield, CO 80021

Topic: *Developing a Quality Culture*

For more information, contact:

Ron Sedlock

the quality Catalyst

Phone: 303-716-5873 or 303-587-9153 (cell)

Email: ronsedlock@thequalitycatalyst.com

**A Conversation with Howard Manresa, Former Director of Compliance, FDA
Denver District Office**

**Wednesday, September 30, 2015 College Hill Library,
Front Range Community College 4:00 pm – 5:30 pm**

3:30 pm – 4:00 pm Registration and Networking 4:00 pm – 5:30 pm Presentation

Rocky Mountain Regulatory Affairs Society is pleased to present Howard Manresa, Former Director of Compliance, Denver District FDA, as our September 2015 speaker. With over 30 years at the FDA, Howard will share his thoughts on new businesses entering into regulated industry, what FDA expects to see when they assess a firm's compliance, how firms respond to inspections and inspectional findings, when you need to consider a consultant, and other topics of interest from the participants.

Speaker Bio Howard Manresa is the business owner of Manresa FDA Consulting, LLC located in Arvada, CO, a consulting service that offers solutions and strategies to firms regulated by the U.S. Food and Drug Administration for establishing, maintaining, or re-establishing compliance with FDA law and regulations. Mr. Manresa retired from the FDA on August, 2014 after over 30 years of service, the last 14 as the Director of the Compliance Branch in the Denver District Office. He was awarded the FDA Distinguished Career Award upon retirement.

He performed as a Consumer Safety Officer, Resident-In-Charge, Supervisory Investigator, and Compliance Officer as follows: Investigator, Los Angeles District Office; Resident-In-Charge, Fargo Resident Post (Fargo, North Dakota); Supervisory Investigator, Minneapolis District Office Compliance Officer, Minneapolis District Office; and Director, Compliance Branch, Denver District Office He currently serves as an instructor, curriculum developer, CAG (Course Advisory Group) member, and expert panel member for the FDA's New Hire Law Training Course, Food and Drug Law II, Practical Compliance Applications, and the "Introduction to FDA Fundamentals for ORA Mission Support Professionals".

Please RSVP to programs@rmras.org Location: Front Range Community College Room L-

211, College Hill Library Westminster, Colorado 303-404-5539  303-404-5539

Directions from Denver: Take I-25 to Hwy 36 toward Boulder. Take Hwy 36 to Sheridan Blvd, exit north. Stay on Sheridan to 112th Avenue, turn east. Go ½ mile and Front Range Community College will be on your left Turn left into the first street into the parking lot and enter the building at the main entrance. Go left through the Library, and Room L-211 will be on your left.

Directions from Boulder: South on Highway 36 to 104th Avenue (Church Ranch Blvd) exit. East on 104th Avenue one mile to Sheridan Blvd. North on Sheridan Blvd to 112th Avenue. East on 112th Avenue, go .5 mile – Front Range will be on your left. Turn left into the first street into the parking lot and enter the building at the main entrance. Go left through the Library, and Room L-211 will be on your left.

Quality-Related Career Openings / New Job Postings



Quark Pharmaceuticals

Division/Department	Boulder/Quality Assurance		
Location	Boulder, CO		
Job Title	Quality Assurance Manager		
Reports to	Associate Director of Quality Assurance		
Date Created	8/01/15		
Type of position:	Hours 40 / week	Band	Zone
<input checked="" type="checkbox"/> Full-time	<input checked="" type="checkbox"/> Exempt	<input type="checkbox"/> 1	<input type="checkbox"/> A
<input type="checkbox"/> Part-time	<input type="checkbox"/> Nonexempt	<input type="checkbox"/> 2	<input type="checkbox"/> B
<input type="checkbox"/> Contractor		<input type="checkbox"/> 3	<input type="checkbox"/> C

General Description

The primary responsibility of the QA Manager will be to assure the compliance and quality of drug substance and drug product manufacturing and testing activities with respect to procedures and applicable domestic and international regulatory expectations and requirements.

- Ensure the compliance of manufacturing and testing activities with respect to company procedures as well as FDA, EU, ICH, and other regulatory expectations and requirements
- Perform batch record review and lot disposition activities for intermediates, drug substance and drug product
- Perform review of analytical data and testing records for intermediates, drug substance and drug product
- Perform review of stability data and testing records for drug substance and drug product
- Provide quality input for failure analysis, problem solving, and risk assessment and mitigation activities related to the manufacture or testing of intermediates, drug substance and drug product.
- Resolve moderately complex deviations, including Out-of-Specification / Out-of-Trend investigations, or any other quality events
- Execute current Quality Systems procedures (auditing, change control, corrective and preventive actions, deviations, investigations, vendor qualification, etc.)
- Maintain employee training program
- Provide support to development groups regarding process and analytical method transfer activities
- Provide quality oversight of contract manufacturing organizations
- Perform external audits of suppliers, contract manufacturing organizations, and contract testing laboratories, clinical research organizations as necessary
- Ability to perform GCP document audits to ensure regulatory compliance
- Provide GCP compliance interpretation and other supportive services necessary to maintain regulatory compliance
- Excellent problem solving and communication skills
- Ability to interface with all levels of management
- Ability to manage multiple priorities with aggressive timelines at a high level of productivity in a fast-paced environment
- Promote quality culture throughout the organization
- Ensure progress and completion of responsibilities in accordance with established departmental goals and project plans
- Identify and implement continuous improvement initiatives that seek to eliminate inefficiency, reduce cost

and improve product quality.

work experience requirements

- 7 years experience in pharmaceutical or biotechnology industry with 5 years of direct responsibility in Quality Assurance.
- Phase 3/NDA experience preferred
- Knowledge of FDA, EU, and ICH regulatory requirements and guidelines related to GMP and GCP operations
- API and drug product formulation, aseptic filling, and finishing experience.

education requirements

- Bachelors of science degree in a scientific discipline or equivalent

Interested candidates should submit their resumes to: hr_us@quarkpharma.com



Rocky Mountain Performance Excellence

P.O. Box 17545 Denver, CO 80217

Phone 303-893-2739 <http://rmpex.org/>

Kim Griffiths, Executive Director: kagriff.kg@gmail.com

Jim Walker, Award Program Director: DrJimW@hotmail.com

