

Volume 26, Issue 4

May 2019

MAY CHAIR MESSAGE

Hi Everyone, we do have a special treat for the May Section Meeting. We'll be meeting at the Boulder Beer Company on Wilderness in Boulder. A drink ticket and appetizers will be provided so that you can enjoy one of Boulder Beer's great brews and their pub menu. We'll be meeting at 5:30pm. This is a chance to grow your professional network in a friendly atmosphere at Colorado's first micro-brewery!

Boulder Beer Company

2880 Wilderness Place Boulder, CO

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

Recertification RUs: Did you see the Facebook meme?



Section Upcoming Meetings Overview:

June - August: Summer break

September - Topic: What it Takes to Become a LSSBB, Dan Clark

Upcoming Opportunities:

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

Quality Tours! Please contact me or Dan Clark if you're interested in giving a tour. Here is a list of a few companies that have provided tours- you could be one of them!

REO (Research Electro-Optics) Fed Ex Boulder Scientific Medtronic Surgical Navigation ... and many more!

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

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

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

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

Best Regards, Joe Wojniak

ASQ Section 1313 Chair joe.wojniak@gmail.com

ASQ's Members and Customers Service Center:

E-MAIL: help@asq.org

PHONE: 800-248-1946

FAX: 414-272-1734

USPS ASQ Communications

MAIL: 600 N. Plankinton Ave.

P.O. Box 3005

Milwaukee, WI 53201-3005

We suggest that you go to the ASQ National website at: www.asq.org for complete ASQ national news, regional event(s) links, books, courses, yearly certification testing, re-certifications, conferences, ASQ Divisions and on-line membership forms which include member upgrades and that which is needed to update your own member profile. And, while you are on the internet, be sure to visit the ASQ Boulder Section website at: <http://asqBoulder.org>

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

ASQ #1313 Officers & Committee Chairs 2019

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Title: Secretary Name: Bill Dunford Phone 720-340-0454 bdunfordASQ@gmail.com	Title: Treasurer Name : Caroline Corwine Phone : 303-912-7327 carolinecorwine@yahoo.com		
Title: Re-Certification Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	Title: Internet & Website Name: Arnold Miller Phone: 303-466-2631 arnold.miller0@gmail.com		
Title: Publicity and VOC Name: Byron Murray byron.murray@yahoo.com	Title: Education Chair Name: Dan Clark Phone: 720-326-8240 dpclark@live.com		
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Title: 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,

End of the Section's 2019 Spring Term on Thurs, May 23rd

Location:

[Boulder Beer Company](#)

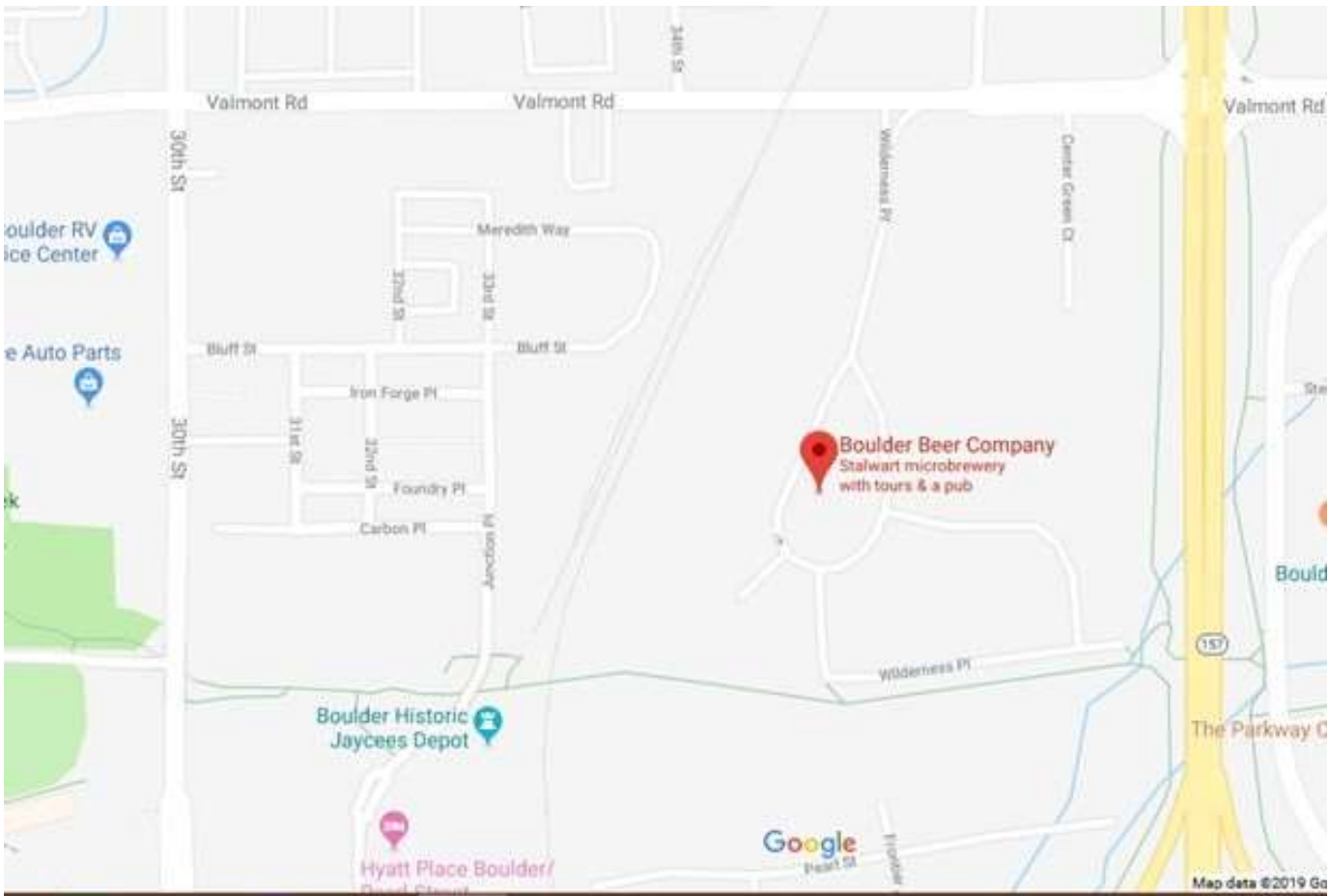
2880 Wilderness Place Boulder, CO 80301

https://en.wikipedia.org/wiki/Boulder_Beer_Company (map below).

5:30pm Doors Open: Networking 7:30pm Meeting Finished

The ASQ Section will provide steam-table items and one beverage ticket for an in-house draft beer of your choice.

- *Must be 21, please carry your ID with you, in case you are asked. Any wine, spirits or other type of food from their restaurant menu, is a la carte per attendee. Thanks.*
- *The Hwy 157 indicated in the map below is the Foothills Parkway. Wilderness Place is immediately south of and accessed only from Valmont Ave.*



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.

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



Dear Certification Holder,

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

Specifically, the new process will:

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

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

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



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

CONNECT With Quality Leaders and Peers:



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@earhlink.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/)

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

➤ Don't Forget to access your Member Gift Online



The screenshot displays the ASQ website interface. On the left, a green sidebar titled 'WHAT DO YOU WANT TO DO?' contains three main categories: 'BUILD MY EXPERTISE', 'DEVELOP MY ORGANIZATION', and 'CONNECT'. Under 'BUILD MY EXPERTISE', there are sub-sections for 'LEARN' (Training, Learn About Quality, ASQ TV, Why ASQ), 'CERTIFY' (Certification), and 'CONNECT' (Communities, Career Center, Ask a Librarian, Blog, Get Involved). Under 'DEVELOP MY ORGANIZATION', there are links for 'Quality Resources' (Books & Standards, Quality Progress, Emerging Quality Leaders Program) and 'Guide to Certification (PDF)'. On the right, a blue banner for 'MARCH 2019 MEMBER GIFT: CUSTOMER EXPERIENCE MANAGEMENT' features a 'ACCESS MY GIFT' button. Below this is a section titled 'Download the Member Gift' with a 'LEARN MORE' button. The background of the right section shows a person's hands typing on a laptop keyboard next to a coffee cup.

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.

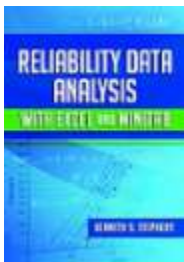


Bestseller!

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 10May2019

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	August 2 - 18, 2019	July 5, 2019	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631	\$400 members / \$450 others	August 2 - 18, 2019	July 5, 2019	TBD	TBD

- (1) Course fee for ASQ or other professional society member/non-member.
- (2) Cost of primers, texts, work-books, etc. are not included and must be purchased by the student prior the first class.
- (3) See ASQ webpage for other certifications and test window dates. <http://asq.org/cert/dates>
- (4) Contact the Boulder Education Chair, Dan Clark (720) 326-8240 <http://asqBoulder.org> If there is a class you need but is not listed above. We may be able to offer that class in the future.

COURSE REGISTRATION INFORMATION

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

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

ASQ #1313 COURSE REGISTRATION FORM

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

Student's Name: _____ ASQ Membership #: _____

or other Society and #: _____

Company Name: _____

Address: _____

Daytime phone: _____ Night time phone: _____

E-Mail: _____ or FAX: _____

Course # and Name: _____

Course Start Date: _____

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

Please enclose a check payable to "**ASQ Boulder Section**" and send check to: **ASQ-Boulder Education c/o Boulder ASQ Section P.O. Box 3783 Boulder, CO 80307**

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

GUARANTEE:

If you pay for and take one of our ASQ Certification review courses and still fail the Certification Exam, you may retake the course for free as many times as you need. The instructor reserves the right to charge for course materials (e.g., handouts, etc.). Your ASQ section leadership is committed to meeting your quality-related education and certification needs. If you have any questions about a particular course, please contact the instructor or the Boulder Section Education Chair (contact information above).

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

From: Ron Sedlock, the quality Catalyst

ASQ Certification Advice

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

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

Cavendish Scott, Inc.

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

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

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

984 S Vine St. Denver, CO 80209

phone: (303) 480-0111

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

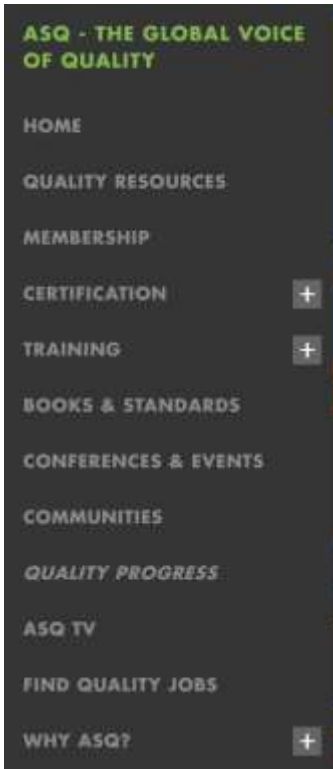
RMRAS Rocky Mountain Regulatory Affairs Society. RMRAS is the premier local professional society in the Denver & Front Range area for individuals involved in medical devices or pharmaceutical industries. Membership is free of charge. And, our two societies' recertification units (RU's) are reciprocal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

Quality-Related Career Openings / New Job Postings

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

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

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



Job Ad
Director of Regulatory Affairs

The Director of Regulatory Affairs will be responsible for the leadership and oversight of the Regulatory Affairs Department and staff of six to ten professionals. The Director will be responsible for the day-to-day planning and oversight of all consulting assignments and client deliverables from CBR Regulatory staff as well as development and maintenance of CBR Regulatory Systems. This position has a career progression to Senior Director of Regulatory Affairs and Vice President of Regulatory Affairs.

Additional Job Requirements:

- Advanced degree in a science, toxicology, pharmacology, engineering, or related field – preferred
- 5 - 10 years of experience in the FDA regulated industry for biologics and small molecules
- Experience with Devices – preferred
- Some supervisory experience is required
- Knowledge and understanding of FDA regulations, ICH guidelines, and global industry standards for the development of regulated investigational products
- Skills in leading complex technical programs and managing multiple projects simultaneously
- Ability to work collaboratively with CBR staff and clients
- Ability to provide clear, concise oral and written communications
- Comply with and support all company policies and procedures, safety and security rules, and standards of professionalism
- Maintain a relevant professional membership (ISPE, PDA, RAPS, RMRAS, etc.)
- Maintain company confidentiality
- Valid driver's license and insurance
- Maintain a valid passport

About CBR International

With offices in Boulder, Denver, Fort Collins, Atlanta, and Berlin (CBR Biotech Strategies), **CBR International** is a global regulatory development company providing comprehensive product development services to the biotechnology and pharmaceutical industries worldwide. Our expert staff is knowledgeable in an all-encompassing range of indications for drugs, novel antibodies, recombinant protein therapeutics, small molecules, vaccines, cell therapy, medical devices, and combination products throughout all phases of program development (Phases I - IV) and commercialization.

We value our amazing staff of professionals, as well as our clients, who together help to bring cutting-edge science and innovative biotechnology products to populations around the world. We *are* making a difference. CBR International has a mission to work with local and global partners to develop strategies that result in achieving successful product, clinical, and regulatory programs. We are committed to creating an environment of team-building, learning, and professional development, which enables us to better advance long-term goals for CBR clients and staff.

Why CBR International is the Fit for You

Ask yourself this: Do you enjoy challenging yourself intellectually? Learning about the latest and greatest technologies that science and biotech have to offer? How about traveling, seeing the world, and learning about global pharmaceutical development? CBR offers competitive salaries and great benefits, including: medical, dental, vision, matching 401K, company-sponsored events, wellness benefits, corporate health club membership, professional development opportunities, professional memberships, and so much more.

Interested in Applying

Please send a resume and cover letter to HR@cbrintl.com and include reference number #19001R. We are excited to hear from you!



Sr Quality Systems Specialist

For more than 20 years, AlloSource's allografts have been the biologic solutions our surgeon customers use to deliver better care to their patients. As one of the largest and most respected nonprofit tissue banks in the United States, AlloSource develops, processes and distributes over 200 types of life-saving and life-enhancing allografts for use in a variety of medical procedures. Our commitment to honoring the gift of tissue donation motivates us to develop innovative allografts and lead the way in cellular and tissue therapies.

Summary:

The Sr Quality System Specialist will serve as the Quality Subject Matter Expert and Trainer for specific processes within the Quality System. Makes decisions based upon knowledge and experience, with regulatory compliance and the integrity of AlloSource at the forefront of consideration. They oversee, manage, and maintain a specific process within the Quality System (i.e., CAPA, NC, Change Control, Document Control, Training Compliance, Quarantine, Equipment Management), and provide guidance and advice to AlloSource personnel related to that system. Identifies and resolves training discrepancies, and evaluate, recommend, and implement improvements for the department's processes, based on standards & regulations, change controls, corrective & preventive actions, and process improvement projects.

Essential Duties and Responsibilities:

1. Administer AlloSource's Quality Management System (QMS) Process.
 - a. Serve as the organization's system expert for representative system during internal and external audits.
 - b. Perform regular audits of Quality System Process to ensure system processes are operating in accordance with controlled procedures
 - c. Initial point of contact for end users in terms of document control, training, system functionality, process set up requirements, and resolution of discrepancies.
 - d. Review submissions to Quality Management System (QMS) for spelling, punctuation, formatting and assure appropriate review and approval.
 - e. Perform system configuration updates
2. Manage and maintain updates to the system.
 - a. Ensure data integrity and document/file accessibility.
 - b. Ensure data adheres to company policy and meets regulatory requirements.
 - c. Approve and perform system configuration administrative updates
 - d. Draft detailed validation testing protocols outlining system requirements, when needed.
3. Serve as the technical expert for a specific Quality Management System process.
 - a. Provide a central contact point for all document control issues, support, and ongoing management of the system.
 - b. Effectively train, mentor and advise all company personnel on the specified Quality Management System.
 - c. Address end user questions promptly with a professional and courteous demeanor.

- d. Confer with document owners and department managers to establish process set-up requirements and resolve discrepancies as needed.
4. Manage and maintain specified QMS related policies and procedures.
 - a. Establish and implement policies and procedures and update them as they evolve.
 - b. Communicate issues related to the QMS to management as needed.
 - c. Provide periodic productivity and compliance reports to Management, and compile/analyze data presented at Quarterly Management Review meetings.
5. Serve as the Business Process Owner of the specified Quality Management System.
 - a. Oversee and implement improvements/upgrades to the system
 - b. Evaluate and enhance current processes in all areas of the company for improved efficiency, automation and increased productivity.
 - c. Lead correspondence of the automated Quality Management Systems (SmartSolve) with the service provider.
 - d. Create User requirements specifications
 - e. Prepare and execute validation testing protocols
 - f. Adhere to and promote proper practices and techniques which are consistent with current operating procedures, training requirements, safety practices and company policies.
 - g. Oversee execution of validation testing and analyze results of pre-determined testing criteria.

Requirements:

- Bachelor's degree in biological sciences, or similar field.
- In lieu of degree, 7 years' working in an FDA regulated industry.
- Successful completion of AATB Certification required within one year of accepting role.
- 5 years' experience working with quality records in an FDA regulated industry.
- 3 years' working with specified QMS.
- 3 years' technical writing experience.
- Advanced proficiency in Microsoft Applications, specifically Excel, Word and Outlook.

TO APPLY:

Please visit www.allosource.org and click on "careers", then "opportunities". Complete your application and submit a resume for consideration

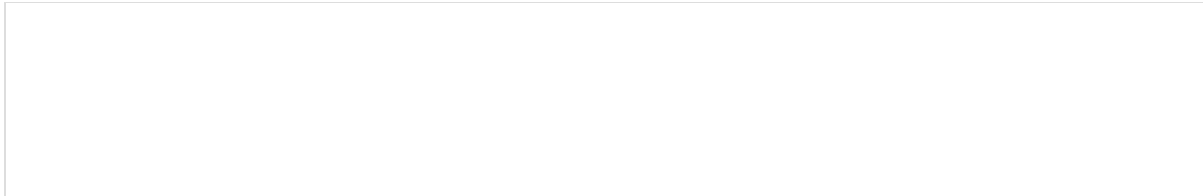
For consideration you must apply online, submit a current resume and meet the minimum requirements. All offers are contingent upon a background check, drug screen and other contingencies may apply depending upon the position. Candidates within a 50 mile radius of the hiring zip code may receive first consideration. If you require special accommodations, please contact us at 720-873-0213.

Equal Opportunity Employer/Veterans/Disability

AlloSource uses E-Verify to confirm the employment eligibility of all newly hired employees. To learn more about E-Verify, including your rights and responsibilities, please visit www.dhs.gov/E-Verify.

Make plans to experience next year's 2020 RMPEX event first hand

<http://rmpex.org/>



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 in May of 2020 in Broomfield, CO
Check the RMPEX website starting in February of 2020.**

Rocky Mountain Performance Excellence ■ P.O. Box 17545 Denver, CO 80217 ■ 303-893-2739

<http://rmpex.org/>