

OCTOBER CHAIR MESSAGE

Welcome to the 2016-2017 season for ASQ. I'm sorry to see the summer season begin it's peek-a-boo with Fall but that is the way things work in these parts. It just means we are "moving on" and the ASQ section meetings and tours will be resuming in September. Your committee has been hard at work developing a meeting and education program for the year. It is always a work in progress; I believe you'll find it very interesting and educational. Our plan is to maintain the alternating speaker/tour program as the year unfolds.

What's new in ASQ? Well, the big thing that potentially affects us all is that ASQ has transitioned to computer-based testing as part of its certification process. No longer will the section set-up and proctor tests at various locations on certain Saturdays. ASQ National now drives this process - you can read all about it in our section's newsletters, e-mails, and on our website at <http://asqboulder.org/certification/>

Speaking of "moving on", my term as section chair ends on New Year's Eve this year and the section is in need of a replacement. If you are interested in serving in this position or any other position within the section, please contact Joe Wojniak at joe.wojniak@gmail.com.

Joe can tell you more about the positions available and where you go to learn more about them (ASQ has some wonderful leadership training materials). 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 quality, Dan Clark

December Spouses Night –on Dec 14th

We have 12 seats available for the BDT production of "Thoroughly Modern Millie" as our annual Dec Meeting on Wed, Dec 14th, starts 5:30pm. Seats are \$22 each (50% off) and includes base-dinner and show. On first come first serve basis, At least one of the two attendees must be a paid-up Boulder Section member. Contact Gerry Naugle at: 303-591-2830 (or gnaugle@earthlink.net) to RSVP. Payment to "ASQ Boulder Section" then locks-in your RSVP to a firm-reservation.

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

The Role of Quality in Education

To continue their support of quality in education, ASQ Section 1106 is also sponsoring two area school superintendents for this year's ASQ Quality Education Conference and Workshop (QECW), November 11 – 13, 2016, in Houston, TX. Share with your members the top 10 reasons to attend the QECW and read an interview with the kick-off keynote speaker, ASQ chief executive officer Bill Troy. For more information on this topic, go to www.asq.org

ASQ National and Boulder Section News is continued on page 4

ASQ #1313 Officers & Committee Chairs 2016

ASQ Section 1313		Boulder, CO	
Title: Chair Name: Dan Clark Phone: 720-326-8240 dpclark@live.com	Title: Vice Chair Name: (open) Phone:		
Title: Secretary Name: Mark Norby Phone: 303-884-4783 mnorby@indra.com	Title: Treasurer Name: John Beachman Phone: 720-313-2746 jbbeach303@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: Nixion Mead Phone: 720-320-6395 nixionmead@q.com			

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Online Content Exclusively for Members:

Member Gift Bundles: Check at the ASQ Website

- **August 2016 Gift Bundle: Cost of Quality**
- [An Introduction to the Cost of Quality Webcast](#)
- [The Executive Guide to Understanding and Implementing Quality Cost Programs](#) (e-book, 128 pages)
- [Principles of Quality Costs, 3rd Edition – Principles, Implementation, and Use](#) (e-book, 219 pages)

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

Online
Blended Training

Lean and Six Sigma

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

Upcoming October 2016 ASQ Boulder Section Meeting

Thurs, Oct 27th

Tour of: Circle Graphics, Inc.

5:30 pm – 7:30 pm 120 9th Avenue, Longmont, CO Cost: Free RSVP on Section's "Meet-up Link"
Suggest to arrive 15 minutes early to sign-in 5:30pm Networking 6:05pm Welcome to Section 6:15pm

Presentation Speaker: Circle Graphics' Quality Dept Topic: Plant Tour 7:30pm meeting over

Directions From Boulder: Take HWY 119 to Longmont Turn Left (North) on US 287 (Main St) Turn Right (East) on 9th Ave On Left Side (North) between Atwood St and Baker St. See map below.



RMPEX Rocky Mountain Performance Excellence Program (*which is also the Colorado State Quality and Business Performance Program*). Please see articles starting on page 15 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://rmras.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 two societies' recertification units (RUs) are reciprocal and interchangeable.

News continued from page 1

ASQ National – and – Local ASQ Section’s News

Denver ASQ Presents The Rocky Mountain Quality Conference

A Virtual Conferencing Experience

Sponsored by SSD Global Solutions, Inc. 

Presented by:



Sponsored by:



SSD Global Solutions, Inc
Accelerated Lean Six Sigma
Training and Consulting

Register to Attend:

www.RMQC.org

Sponsor or Exhibitor
Information Contact:

Terra Vanzant Stern, PhD,
Chair RMQC

Terra.Stern@SSDGlobal.net
303 575-1265

Rocky Mountain Quality Conference

Conference Dates: November 3-4, 2016
Post Workshops: November 5, 2016

A Virtual Experience!

*Live Instruction in Real Time on Your Computer or
Mobile Device
No Special Equipment Necessary!*

Keynote Speakers

Forrest W. Breyfogle III, President, Smarter Solutions, Inc.
JR McGee, X-Stream Leadership

Opening Session

Jay Arthur, President, QI Macros
Terra Vanzant Stern, PhD, Principal, SSD Global Solutions, Inc.

Five Informative Tracks

Government
Healthcare
Project Management
Lean Organization
Professional Development

Prizes – Giveaways – Networking Opportunities

Early Bird: \$199.00 (thru 9/12/2016)
General Registration: \$239.00 (9/13/16-10/15/2016)
Late Registration \$289.00 (after 10/15/2016)

US Veteran and Group Discounts Available

www.RMQC.org

Keynote Speakers



Forrest Breyfogle

President of Smarter Solutions, Inc.



JR McGee

X-Stream Leadership Group



RMQC
Rocky Mountain Quality
Conference

Opening Speakers:

Jay Arthur president and CEO of KnowWhere International Inc.

Terra Vanzant Stern PHD. president of SSD Global Solutions, Inc.

[Full List of Speakers](#)

Five Informative Tracks to Choose From:

Government

Healthcare

Project Management

Lean Organization

Professional Development

Rocky Mountain Quality Consortium | P.O. Box 849 Conifer, CO 80433 |

720-506-4263  720-506-4263



Need to Know

A Celebration of 70 years

Throughout 2016, ASQ will be marking its 70th anniversary. As part of the celebration, ASQ is inviting members to submit their earliest or most memorable experience as a member of ASQ's global quality community. We'll compile an online collection of anecdotes you'll see throughout 2016 and beyond. Photos are also welcome; we can post one alongside each special memory.

Experience ASQ Computer-Based Testing



Now that ASQ has transitioned to computer-based testing, you have the unique opportunity to share with your members a demonstration of the test experience. The demo allows you and your members to experience the look and feel of the test platform that will be used for computer-based test delivery at Prometric test sites.

[View the test demo here >](#)

[Learn more about CBT >](#)

ASQ Boulder Section is seeking a Section Vice-Chair volunteer(s) in 2016. An opportunity to perform important ASQ volunteer work, and receive 1.5 RU's per year in return for your assistance.

Contact Section Chair Dan Clark, at: (720) 326-8240 Thanks!

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>

Updates to ASQ Re-cert Journal & Cost- Increase for 2016

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 much 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 2016-17!

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

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.

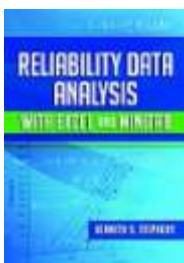


Bestseller!

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.

2016 ASQ Boulder Section Course Offerings

Updated 06Oct2016

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	6/4/2016	4/15/2016	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631 Location: TBD	\$400 members / \$450 others	6/4/2016	4/15/2016	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	10/1/2016	8/12/2016	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	10/1/2016	8/12/2016	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	6/4/2016	4/15/2016	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> 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 Joe Wojniak**, Phone: 970-619-9395 (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

My availability is somewhat limited for 2016, but let me know if you have any training needs. I do exam preparation classes for most **ASQ Certification Exams**. You should begin the exam preparation at least three months prior to any exam. If you have 6 or more people seeking certification, I can provide in-house training.

Also I offer other courses which give more detail on quality improvement. Understanding **Statistics** and effective **Auditing** techniques are subject matters I specialize in. On your own? I give advice on exam preparation and quality in general. **This is a free service**. It is my way of giving back to the profession that has served me well for 40 years. Have a great 2016!

Ron Sedlock, the quality Catalyst phone: 303.587.9153

www.thequalitycatalyst.com

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. Please pass on this information as appropriate.

Date: Thursday, October 20, 2016 Time: 1:00 to 5:00 pm

Location: Coors Brewery, Golden, CO Topic: Building a Just Culture

For more information, contact

Ron Sedlock, the quality Catalyst Ph: 303-587-9153  303-587-9153 ronsedlock@thequalitycatalyst.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

(303) 480-0111

Quality-Related Career Openings / New Job Postings

Cavendish Scott, Inc Job Openings November 2016

ASSOCIATE/CONTRACT ISO AUDITOR(S)

Cavendish Scott is interested in establishing good relationships with professional, reliable and trustworthy professional auditors. We need help to cope with fluctuations that occasionally occur in our business and can sometimes provide more consistent assignments.

Ideally you would be a current auditing contractor, with an established workload of audits and are wishing to supplement that. Ideally your focus would be on auditing so that you have a clear development goal, and would not be consulting in ISO implementation or at least not significantly. We consider this to present a potential conflict although its not insurmountable.

You should like travel because that is one of our most difficult situations that we have to address.

You should probably have an IRCA or EG auditor card – or an equivalent independent way of demonstrating your competency and professionalism.

Personality and loyalty are paramount. You have to operate as part of a team and fit in with our established processes and methods.

ENTRY LEVEL ISO AUDITOR

Cavendish Scott is looking for additional resources in the form of an entry level ISO auditor. We see this as an entry position, with plenty of support provided and firstly focusing on auditing and then developing into training and consulting if desired and as opportunities arise and competency is established.

Ideally you will have some experience of ISO 9001 (maybe similar standards such as FDA). You may have been involved in the implementation of ISO 9001 (or similar) or been responsible for its upkeep and maintenance. You may have conducted internal audits and been responsible for interfacing with the certification body. Perhaps you have even performed audits for a certification body. Ideally, you would have had some managerial experience (oversight of the QMS may be enough but other formal experience might be equally useful). You should be familiar with most/all typical organization processes and be comfortable talking with management about ISO and relevant topics.

You must be confident and comfortable presenting in order to be able to fill the role of auditor.

You will be an effective writer possibly having written procedures, instructions and management reports.

Personality is critical to us. You will be easy going, dynamic, self-motivated, self-starter, hardworking, and capable of standing alone. You also cannot be afraid of new standards, situations or challenges. You will be given support but you have to be able to act professionally and come up with solutions on your own.

We need someone who is available to travel. Even likes travel. The job minimally would require 14-16 trips a year of 2-3 days on average. But plan on being able to cope with an average of two trips a month of 3+ days (this is not what we currently do but you never know).

We will provide training and support to develop the right candidate to a fully qualified ISO professional (it's not just 9001 but AS9100, 13485, R2, 27001, 45001, 18001, 17025 to mention but a few).

We are not particularly looking for a contractor or part time person to fill this position – but try us.

The job is great! You will learn all about/get exposure to a variety of organizations, management systems, standards and so many other things you get exposed to. You get to meet some really cool people and work from home. Conversely you are expected to work the hours you need to in order to satisfy your customers (they tend to work normal hours) and then work more to make sure you answer emails, stay responsive and do what needs to be done to be successful. This is NOT a 9-5 job and sometimes deadlines will mean you have to put extra hours in. Historically there has been plenty of free time to develop your skills, help develop training material, work on marketing and presentations, etc. You manage yourself and the compensation package is probably more than is generally available. Benefits include health, 401k, disability. All work expenses are paid. All equipment (phone, computer, etc.) are provided.

Application

To apply please briefly email us and tell us why you are right for the position. Some of the technical requirements for the job are important but personality and overall ability are probably better things to convince us of. Let's keep it to 10 email lines (about 300 words). No resumes, no application forms. We'll see where it goes from there.

Cavendish Scott, Inc.

Info@cavendishscott.com

Vitrolife Inc.

VALIDATION SPECIALIST (DENVER)

[Send application](#)

We are looking for an employee who is responsible for Validations for our Englewood, Colorado location.

Responsibilities

- Maintain the Validation Plan and Schedule
- Write equipment and process validation programs, protocols, reports and assessments
- Provide engineering and maintenance assistance for equipment such as autoclaves, dry heat sterilizers, cold rooms, incubators, lab equipment, HVAC, air compressors, and water system within a production environment including a cleanroom
- Writes equipment and process SOP's
- Process and support the organization in NC handling, change controls, and document control

Successful Attributes

- Service-oriented
- Accurate with strong attention to detail
- Energetic, self-motivated, analytic
- Ability to work within a team
- Ability to foresee, prevent and solve problems
- Manage multiple priorities and advanced tasks
- Strong written and verbal skills
- Experience with statistical analysis
- Strong computer skills including Excel, Word; LIMS and Quality System software experience a plus
- Direct experience working in a cleanroom is desirable
- Ability to lift up to 30 lbs.

Background

- Bachelor's degree in Engineering, Life Science or Computer Science related field and/or equivalent combination of education and experience
- Must have a minimum of two (2) to four (4) years of experience in a cGMP/FDA manufacturing facility and 1-3 years direct validation experience.

- Work related competence: Writing and performing validations, technical / scientific report writing and working with quality systems in a cGMP environment

Candidates should be US citizens or have permanent resident status.

The salary for this position is competitive commensurate with experience. Vitrolife, Inc. benefits includes health, dental, life, AD&D, short and long term disability insurance; paid time off programs, and the opportunity to work with a talented, inspired and energetic workforce.

If you meet our requirements and would like to be considered for this full-time position, contact us via e-mail with your resume, cover letter and salary expectation at <mailto:hруса@vitrolife.com>

Vitrolife, Inc. is an Equal Employment Opportunity Employer

Terumbo BCT

Clinical Evaluation Reporting Specialist

The Clinical Evaluation Reporting Specialist is responsible for writing Clinical Evaluation Reports (CERs) for Terumo BCT products. The Specialist relies on clinical data, published literature, complaints, and adverse event reporting to create the CERs. A number of personnel from different departments will contribute documentation necessary for completion of a CER. The Specialist brings these individuals together and directs them regarding the information needed for CERs. The Specialist will be responsible for the final compilation/authoring of new CERs and annual CER updates.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Lead the development of CERs by bringing together various stakeholders (eg, Quality Assurance, Regulatory Affairs, Clinical Affairs, Clinical Research Scientists, Pre-clinical Research Scientists, and literature search representatives [eg Terumo BCT librarians]) to identify relevant documentation needed for the content of CERs.
- Collaborate with the literature search representatives to conduct literature searches on Terumo BCT products and product families, and identified predicate and competitor products
- Review the published literature to identify articles applicable to the safety and performance of Terumo BCT products.
- Cross-lane collaboration to 1) understand regulatory submissions and priorities, 2) compile product complaints for both equipment and disposables, 3) conduct Adverse Event Reporting searches on Terumo products and product families and identified predicate and competitor products, and 4) compile clinical data, including Clinical Investigation Protocols and Clinical Study Reports, for Clinical Investigations
- Author the first draft of new CERs and annual CER updates for Terumo BCT products, according to business and research priorities
- Manage CERs document reviews, reconcile major review comments and concerns, and manage finalization and approval of the CER
- Collaborate with Clinical Research Scientist and Lead Pre-clinical Scientist on relevant cross-functional teams to provide input on risk management deliverables, clinical research and literature evidence for product development process needs

OTHER DUTIES AND RESPONSIBILITIES

- Remain current in Clinical Evaluation Report regulatory requirements for all applicable countries
- Develop policies/procedures related to Clinical Evaluation Reviews and Reporting, as needed
- Work with contractor(s) to guide development and update of Clinical Evaluation Reports, as needed
- Disseminate findings quantified in the update process of Clinical Evaluation Reports
- Develops Clinical Evaluation Report logistics such as deliverables, timelines and draft reviews

- This position is required to assure compliance of Company operations to all applicable laws, regulations, and standards, good business practices and company documented procedures

MINIMUM QUALIFICATION REQUIREMENTS

Education

Bachelor's degree in biological or medical science is required or equivalent of education and experience sufficient to successfully perform the essential functions of the job may be considered

- PhD in a scientific discipline preferred.

Experience

- Minimum 2 years technical writing or clinical evaluation reporting experience in academic or the medical device/pharmaceutical industry in clinical or regulatory roles
- The Specialist has experience and understanding of clinical research and regulatory guidelines

Skills

- Possess leadership skills
- Possess interpersonal savvy and ability to develop and maintain crucial interdepartmental relationships
- Work effectively alone and with minimal direction or supervision as well as function effectively as a part of a multi-disciplinary team
- Effectively prioritize and progress multiple simultaneous priority projects and demands
- Able to present concepts and information to a wide variety of disciplines and functions related to CER content
- Develop and implement global policies and procedures
- Analyze information coming from multiple internal and external sources
- Solid understanding of scientific/clinical research methodology
- In-depth knowledge of regulatory process (CE Marking, IDE, PMA, 510(k), post-market/post approval), GCP procedures, and legal compliance for pharmaceutical and/or medical device industry
- Demonstrated ability to utilize a variety of software programs (e.g., Microsoft Office, Excel, Word, PowerPoint, Access)
- Demonstrated writing capability and critique of clinical and regulatory documentation
- Program/project management skills for effective project execution and management
- Facility with general writing and presentation software

PHYSICAL REQUIREMENTS

Typical Office Environment requirements include: reading, speaking, hearing, close vision, walking, bending, sitting, and occasional lifting up to 20 pounds.

The physical demands described here are representative of those that must be met by an associate to successfully perform the essential duties of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

We are proud to be an Equal Opportunity Affirmative Action Employer. All applicants will be afforded equal opportunity without discrimination because of race, color, religion, sex, sexual orientation, marital status, order of protection status, national origin or ancestry, citizenship status, age, physical or mental disability unrelated to ability, military status or an unfavorable discharge from military service.

We maintain a drug-free workplace and perform pre-employment substance abuse testing and background verification checks. As of January 1, 2017 the Terumo BCT Lakewood, Colorado location will be a tobacco-free workplace. For more information about Terumo BCT, visit our website www.terumobct.com/careers.

Join Terumo BCT as we unlock the potential of blood. We are the world leader in blood component technology, delivering products, services and solutions for customers and their patients worldwide. Through collaboration with our

customers and a commitment to innovation, we are the only company with the unique combination of apheresis, manual and automated whole blood processing and pathogen reduction technologies coupled with robust technology, innovation and core competencies in therapeutic apheresis, cell collections and cell processing.

As the largest medical device manufacturing company headquartered in Colorado, we are home to more than 2,300 associates and our products are in use in more than 125 countries and territories. Our Global footprint includes more than 5,500 associates and partners with regional headquarters in Brussels, Buenos Aires, Hong Kong and Tokyo.

Our company has almost \$1B in annual revenues and has been voted and recognized as:

- Largest corporate sponsor in Rocky Mountain Region for Leukemia and Lymphoma Society (LLS)
- Winner of the Association for Talent Development (ATD) BEST Award for providing exceptional employee learning and talent development (2011 & 2012)
- One of Colorado's Healthiest Employers by *Denver Business Journal* (2014 & 2015)
- Recipient of the *Way to Go* Employer award through the Denver Regional Council of Governments (DRCOG) 2015

Our award-winning culture embraces:

- Leading technology through innovation and R&D
- Wellness programs
- Commitment to quality
- An environment that values, respects and rewards your individual contributions
- A philosophy of intentional growth and responsiveness to world health issues

[Click Here](#) to see what our associates have to say about our culture.

Each associate has a positive impact on our future by:

- Connecting to the lives of the patients we ultimately serve
- Growing through professional and leadership development activities
- Sharing company success through incentive plans

If you are the best at what you do and want to do work that is changing the delivery of healthcare globally, we invite you to work with us now to see how we can unlock your potential.

To apply, please go to: www.terumobct.com and apply for requisition JB-3335.



We are pleased to announce the 2016 RMPEX Award Recipients!

The 2016 RMPEX Quest for Excellence, held May 18, was well-received by the attendees with 98% of survey responses rating it as valuable or very valuable. Speakers covered a range of topics, including experiences with the Baldrige process, lean, six sigma, ISO 9000 and ASQ team excellence awards. A sample of the material presented is provided below; click on the image to view the content.

The 2017 Quest has been scheduled for April 14, 2017, on the Auraria campus in Denver. Make plans to experience next year's event first hand.



Dr. John Latham presents an introduction to organization design and transformation to achieve sustainable excellence. Award-winning frameworks are described.



Adam Cohen summarizes the Baldrige Performance Improvement Process and how organizations use it to improve performance.

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