

Next ASQ Boulder Section Meeting is on Thurs, Jan 28th at Medtronic -- 867 Coal Creek Circle Louisville
Topic is: Where R You on Your Quality Journey?
Doors open at 5:30pm
More meeting details and a map on page 3.

Volume 23, Issue 1

January 2016

JANUARY CHAIR MESSAGE

Happy New Year!!! I hope you all had a wonderful holiday season.

Now that the New Year is upon us, I'm sure that many of you (me included) made resolutions. Most of these, I predict, are the standard ones (lose weight, get into shape, organize your sock drawer, etc.). How many of you resolved to improve quality around you? I'll bet you didn't think of it that way but most of our resolutions lead eventually to quality improvement. How is that, you say? Organizing your workspace or your house will create less mistakes. It's been proven. Reducing waste will reduce the time it takes to produce things or service the customer. Having more "allowed" time to get the job done reduces mistakes. It's been proven. I think you might see the connection here, whether it be at home or on the job (which could be the same for many of us). Preventing errors or mistakes is the root of any good quality system, whether it be quality control, quality assurance, or quality management. I believe that is what many of us were hired to do. Quality and improvement go hand-in-hand and this is one of the connections between quality and lean, as I see it.

I am a member of the Colorado Quality Executive Network (CQEN) which is a group of quality professionals from the Front Range that meet quarterly to discuss issues with quality management and the quality sciences. One item we are planning to wrestle with is the connection between lean and quality. Remember the "compare and contrast" stuff we did in school? This will be a similar exercise. I will be interested to hear what others believe the connection to be. Or not. And I would love to hear your thoughts on the subject.

So, back to your resolutions. Did many of you, purposefully or not, resolve to continue the journey of quality improvement, whether it be by improving inspection or measurement techniques, reducing waste, or simply making a better life for yourself? I hope so. And our section can help you in many ways. Reach out and ask for assistance. Quality professionals love to help. Keep having fun and, again, Happy New Year!!

Yours in quality,
 Dan Clark, ASQ Boulder Section Chair

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



ASQ Industry Research Resources
 Over the past few years ASQ has rolled out three big industry research projects—Global State of Quality Research, ASQ/Forbes Culture of Quality, and 2016 Future of Quality Report.

These reports are all highly relevant and can be used to engage other members, potential members, businesses, and universities. Sharing industry research creates an opportunity to entice, discuss then debate and learn from industry professionals. Download the PPT presentations and other resources on each project 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
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Title: Secretary Name: (open) Phone :	Title: Treasurer Name: John Beachman Phone: 720-313-2746 jjbeach303@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
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Title: Certification Name: Nixon Mead Phone: 720-320-6395 nixonmead@g.com	

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Online Content Exclusively for Members:

Member Gift Bundles: Check at the ASQ Website

- **Jan 2016 Member Gift Bundle: Career Resources**
- [The ASQ 2015 Salary Survey Results and a Special Report on the Impact of Organizational Culture](#) (Webcast)
- **The Quality Improvement Handbook, Second Edition** (eBook)
- **The Executive Guide to Understanding and Implementing Employee Engagement Programs** (eBook)

Download your gift today

Contents




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 January ASQ Boulder Section Meeting

Thurs, Jan 28th at Medtronic -- 867 Coal Creek Circle, Louisville, CO

Note: there are two Medtronic buildings on Coal Creek Circle. 867 is the building on the opposite side of the street from Cablelabs.

Presenters are: Joe Wojniak and Dan Clark, ASQ Boulder Section

Topic: Where R You on Your Quality Journey?

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 **7:30pm** Meeting over

Meeting Location: Training Room #1

Go through entrance to 867 (doors facing south). Take elevator on the left to the 2nd floor. The Training Rooms are through the glass doors & into the reception area- continue to the right.

<https://goo.gl/maps/vK2RB7Ujtjr>



Advanced Tour Planning – March Event

The Section is planning a tour of the Seagate facility in Longmont for the March 24 meeting. We will be receiving an in-depth tour of the entire facility, including their failure analysis lab. We will be exposed to sensitive information and processes.

As a result, we have been asked to limit the tour attendance up to a maximum of 20 members who plan to attend so that security clearance can be completed prior to the tour. If you are interested in learning how the world's premier manufacturer of hard disk drives does it, this is your chance. Access to the tour is restricted in order to comply with the Seagate security protocols and protect their competitive advantage. Tour authorization for individuals is solely at the discretion of Seagate's security personnel.

If you plan to attend, please sign up soon on the meet-up invitation you will receive or send an email with the requested information to Joe Wojniak (joe.wojniak@gmail.com) and provide him with your name and organization represented on or before February 26, 2016.

RMPEX Rocky Mountain Performance Excellence Program (*which is also the Colorado State Quality and Business Performance Program*). Please see articles starting on page 13 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 societies' recertification units (RUs) are reciprocal and interchangeable.

ASQ National – and – Local ASQ Section News

ASQ Boulder Section is seeking a Section Secretary (and) a Section Vice-Chair volunteer(s) in 2016. Two opportunities 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

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.

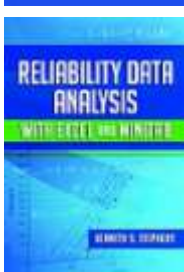


Bestseller!

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 06Jan2016

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	3/5/2016	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	3/5/2016	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	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> 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 #: _____

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, Phone: 970-619-9395 (e-mail 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

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, January 21, 2016 Time: 1:00 to 5:00 pm

Location: HunterDouglas, Broomfield, CO

Topic: The Relationship between Lean and Quality

For more information, contact:

Ron Sedlock, the quality Catalyst

Phone: 303-587-9153  303-587-9153

Email: ronsedlock@thequalitycatalyst.com

Cavendish Scott, Inc.

Cavendish Scott is the Rocky Mountain Region's primary ISO 9001 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 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

There are several QA/QE Positions Open at the Zimmer Biomet Corp -- Broomfield/Interlocken

Quality positions are available at Zimmer Biomet Inc. Please apply at <http://www.zimmer.com/careers.html>

310 Interlocken Parkway, Suite 120 Broomfield, CO 80021 www.zimmerbiomet.com

USAA Insurance Corporation in Colorado Springs, CO

Lean Six Sigma (Process Excellence) Black Belt job posting at USAA in Colorado Springs

search.usajobs.com/us/en-us/Job-Details/Black-Belt-Process-Excellence-Job/Colorado-Springs-CO/XjdP-jf840-ct104391-jid53014094

www.linkedin.com/pulse/were-hiring-infographic-chuck-rohrig?trk=hp-feed-article-title-ppl-follow

GogoAir Business Aviation in Broomfield, CO (Interlocken)

Quality Inspector II

Gogo Business Aviation is the world's leading provider of airborne communications and In-flight entertainment (IFE). Until recently, time spent in the cabin of a business jet meant that you were disconnected from the world circling below. That's all changed. Airborne technology has finally caught up with the rest of the world. Simply put, voice, data, streaming IFE and even the entire Internet can be at your disposal during flight—in the cockpit and in the cabin. Now you can use that time to return calls, answer email, download files, watch a moving on your personal device or simply conduct a little firsthand Internet research.

The **Incoming Inspector (Inspector II)** works as an integral part of the Gogo Business Aviation Quality team performing inspections of materials received from suppliers (new and reworked/repared materials) as part of the Receiving process to ensure that they fulfill all requirements prior to acceptance in to inventory.

COME ON BOARD THE GOGO BUSINESS AVIATION QUALITY ASSURANCE TEAM!

This role consists of, but is not limited to, identification, damage inspection, conformance to design specifications, and documenting findings, as well as initiating and following through on contact with the engineering and/or material suppliers for resolution when there is a discrepancy that is detected. This role may also expand to in-process and final assembly inspection which may consist of workmanship and conformance to drawing and/or process and test instructions. In addition to the technical skills required to adequately perform this role, this position requires a self-starter that will work under limited supervision following general direction for work and may have full responsibility for minor projects.

How will you make a difference?

Inspect and file/record incoming material history records. Perform accurate visual, dimensional, mechanical, and/or functional inspection of materials per inspection plans, drawings, and other specification requirements. Read and interpret specifications, schematics, and/or design drawings. Initiate material nonconformance reports, as required. Ensure that the report contains accurate and sufficient detail of compliance or the cause(s) of failure and recommended correction(s). Work with other personnel, both internal Gogo and external suppliers, to effectively resolve inspection questions and/or issues. As needed, assist with conducting First Article Inspections.

Qualifications

Minimum of a high school diploma. 5+ years of experience in a manufacturing quality control environment utilizing mechanical inspection techniques and familiar with being able to inspect to IPC standard workmanship criteria. American Society of Quality (ASQ) Certified Quality Inspector (CQI) certification

THIS IS A SAFETY SENSITIVE POSITION - SUBJECT TO RANDOM DRUG SCREEN

Required Skills, Experience and Talents

- Knowledge and ability to interpret geometric dimensioning and tolerancing (GD&T). Proficient with geometry and trigonometry (machine shop math).
- Previous visual and mechanical inspection background with the ability to use basic hand measurement tools (Calipers, micrometers, etc.), as well as higher precision measuring, optical inspection, and/or non-destructive evaluation equipment.
- Strong attention to detail and task organizational skills.
- Self-driven to achieve defined goals and metrics, requiring minimal supervision.
- Proficient computer skills with office software applications and a proven ability to use basic data analysis tools.
- Effective teamwork, interpersonal, and communication skills, both written and verbal.
- Professional appearance, good communication skill, team friendly, and approachable. A sense of humor is a plus.
- Ability to lift 50 lbs. Will be working in office, lab and manufacturing environments.

The job is posted at <http://business.gogoair.com/about/careers/job-postings/>

Re: **Rebecca Jessep** Director, Quality [Gogo Business Aviation](#)
105 Edgeview Drive, Suite 300 | Broomfield, CO 80021 | USA | +1 303 301 3337

Auto req ID	10911BR
Title	Staff Quality Engineer
Job Family	Engineering
Location	Boulder, CO
Job Description	The Quality Engineer for Medical Device Development will serve as the focal point for the project team and the customer on topics related to safety agency and regulatory compliance as well as the necessary quality system(s). The Quality Engineer has overall responsibility for assuring that the product is designed and tested in compliance with applicable domestic and international regulatory agencies and/or bodies. This includes but is not limited to: participating in the development of the product specifications, defining project compliance to internal and external standards, coordinating safety agency marking and regulatory compliance, coordinating the risk management and human factors activities, and coordinating design verification test activities.

Key Aspects of your Job:

- Ensure that the planned project activities are compliant with Plexus' standard operating procedures and ISO (i.e. 13485) quality systems, the FDA Quality System Regulation (QSR) regulations.
- Understand Design History File (DHF) content requirements and be capable of performing all aspects of DHF maintenance.
- Support proposal activities for new business and other marketing support as requested.
- Participate in the Plexus quality system development and maintenance.
- Understand medical device safety standards (i.e. IEC 60601-1), regulatory requirements, and be capable of identifying those that are applicable for each unique product.
- Determine appropriate specifications to comply with regulatory and compliance requirements of intended markets.
- Mentor and lead the project team on regulatory and safety agency compliance requirements of intended markets.
- Facilitate documentation of functional, electrical and mechanical specifications.
- Lead the development of the product Risk Management Plan and maintain customer specified content of the Risk Management File for each unique product.
- Lead product Risk Analysis meetings and document the results as specified in ISO 14971. Follow up as required throughout the project to ensure adherence to risk management plan. Risk activities also include coordination of Design Failure Modes and Effect Analysis reports, Fault Tree Analysis, and other risk reports.
- Coordinate device reviews with safety agencies.
- Coordinate all Design Verification Test activities, including generation of the verification Plan, Procedures and Report documents.
- Review design related project documents and drawings to ensure internal and external requirements are met.
- Participate in engineering reviews to ensure they are conducted and documented as appropriate.

What you need to be Successful in your Job:

- Possess a strong working knowledge of medical device and similar safety standards (i.e. IEC 60601-1, IEC 61010-1)
- Possess understanding of regulatory requirements such as FDA Quality System Regulations, ISO 13485 and the EU Medical Device and In Vitro Diagnostic Medical Device Directives
- Experience with the development of risk management planning and analysis as defined in ISO 14971
- Experience with Design Verification Test activities including test planning, test procedure and test report development
- Experience working with safety agency test labs for agency certifications such as UL, CSA, CE, etc.
- Possess at least basic knowledge of the Software Quality Engineering functions
- Possess excellent verbal and written communication skills as well as interpersonal skills necessary to work across multiple engineering disciplines, project management, and external customers.

- Must be able to work in a matrix style organization on multiple projects simultaneously.

Education and Experience

- A Bachelor's degree in a scientific, engineering or equivalent background is required for this position
- Experience of 8 years in quality engineering for medical device product development or equivalent is required for this position

Qualifications

All offers of employment are contingent upon successfully passing a drug screen and upon completion of a confidentiality agreement. Our Values and How We Lead behaviors guide our processes. Plexus does not make employment decisions based on race, color, religion, national origin, sexual orientation, gender identity, disability, or veteran status. We are proud to be an Equal Opportunity Employer (EOE) and encourage all to apply today!

Globally, our policy is to recruit people from wide and diverse backgrounds. Some of our customers contracts are governed by the International Traffic in Arms Regulations (ITAR), which require us to consider only applicants who are US citizens, permanent residents (green card holders), or who have been granted political asylum. Consequently, some of our positions are subject to this ITAR requirement. Thank you for your understanding.

Applicants can apply here:

<https://sjobs.brassring.com/TGWebHost/jobdetails.aspx?partnerid=25631&siteid=5183&AReq=10911BR>



We are pleased to announce the 2015 RMPEX Award Recipients!

Peak Awards

- AlloSource, Centennial , Colorado
- Community Hospital, McCook, Nebraska
- Donor Alliance, Inc., Denver, Colorado

Foothills Award

- El Paso County School District 49, Peyton, Colorado

Please join us in a hearty congratulations to all the RMPEX Award recipients for this past year! And watch for the announcement of our Quest Event where you can hear what these great organizations have accomplished on their journey to performance excellence.

Jim Walker, Award Program Director

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

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

