Boulder Section
The Global Voice of Quality™

Next ASQ Boulder Section meeting will be Thurs, Sept 25th at Covidien/Boulder Building at 6170 Longbow Dr. Bldg #2, doors open at 5:30pm. More details on Pg 3.
Five new Sept '14 job openings, starting on page 10

Volume 21, Issue 1 **September 2014**

SEPT CHAIR MESSAGE

The ASQ Section survey this year provided feedback that many people would like to see examples of the basic Quality tools and learn how they are applied. This month's meeting will focus on case studies. The basic quality tools have a common theme: counting stuff. You can count defects, number of cups of coffee served, anything of interest. If you are not sure where to start, think about what the end objective is. Look for the differences between how things are now and how you'd like them to be. This is the Planning part of Plan-Do-Check-Act. You see what's coming next!

Do! Try some changes out; these can be small steps at first. I am continually surprised at how hard accepting change can be! And I'm including myself in that statement. Since any change, even an improvement, is disrupting the equilibrium of the process there may be a temporary decline in the performance measure. So it's important not to introduce too many changes all at once, unless this is done in a manner where all the different effects can be sorted out. It's also important to implement the change long enough to evaluate the effect. Which brings us to the next step — Check.

Check the effectiveness of the Do step. Part of planning needs to be defining how much of an improve-ment is needed in near term). Now the hard part: you're probably not done yet. The next step is Act. Quite often there are unexpected consequences to the actions we take. A common refinement in the Act step is to lessen or avoid the unexpected consequences of the change(s) made.

What's next? Step back from the immediate goal and re-evaluate the situation. Now that this one area is perform-ing better, is there another area that needs improvement? Do we need to continue to focus in the area where we started? Here is a link to the 7 Basic Quality Tools. Each one has a template and a description for how it's used.
http://asq.org/learn-about-quality/seven-basic-quality-tools/overview/overview.html
I'd like to hear from you- how are you making the world work better?
Best Regards,
Joe Wojniak, ASQ CQE Boulder Section 1313 Chair

●We have four seats available at $22 each for the Dec 17th Boulder Dinner Theater showing of "Fiddler on the Roof". Any dues-paid Boulder member is eligible for two seats on first-come first serve basis, contact Gerry Naugle, at: gnaugle@earthlink.net if you are interested.

ASQ's Members and Customer Service Center:

E-MAIL: help@asq.org

PHONE: 800-248-1946

FAX: 414-272-1734

USPS MAIL: ASQ Communications
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 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 **ASQ Boulder Section website** at: **http://asqBoulder.org**

ASQ National News

Brought Into Focus—ISO 9001:2015 Specifically Addresses Risk

For the first time, the word "risk" is being incorpora-ted into the new 2015 version of ISO 9001. This may require organizations to refine methods for identify-ing, managing, and mitigating risk. The QP (Quality Progress) article in the September Edition discusses this concept, as well as how organizations can ad-dress this change to the standard, including:

Customer focus. Clause 5.1.2 says top manage-ment must "demonstrate leadership and commitment with respect to customer focus by ensuring … the risks and opportunities that can affect products, ser-vices and ability to enhance customer satisfaction are determined and addressed."

News continued on page 4

ASQ #1313 Officers & Committee Chairs 2014-15

ASQ Section 1313	Boulder, CO
Title: Chair Name: Joe Wojniak Phone: 303-530-6581 Joe.wojniak@gmail.com	**Title: Vice Chair** Name: -Position Open- Phone:
Title: Secretary Name: Patricia Fleenor Phone : 303-501-8457 patricia.fleenor@biomet.com	**Title: Treasurer** Name: John Beachman Phone: 720-313-2746 john.beachman@covidien.com
Title: Re-Certification Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	**Title: Internet & Website** Name: Arnold Miller Phone: 303-466-2631 arn_miller@earthlink.net
Title: Publicity and VOC Name: Byron Murray byron.murray@yahoo.com	**Title: SMP** Name: Open Phone:
Title: Financial Auditing Name: Ewald Schelert Phone: 303-702-9009 schelert@mesanetworks.net	**Title: Education Chair** Name: Patricia Fleenor Phone: 303-501-8457 patricia.fleenor@biomet.com
Title: Newsletter Co-Editor Name: Gerry Naugle Phone: 303-591-2830 gnaugle@earthlink.net	**Title: Newsletter Co-Editor** Name: Bill Dunford Phone 720-340-0454 billdunford@hotmail.com
Title: Certification Name: Nixion Mead Phone: 720-320-6395 nixionmead@q.com	**Title: Programs** Name: Dan Clark Phone: 720-326-8240 dpclark@live.com

Contents

Online Content Exclusively for Members:

ASQ Member Gift

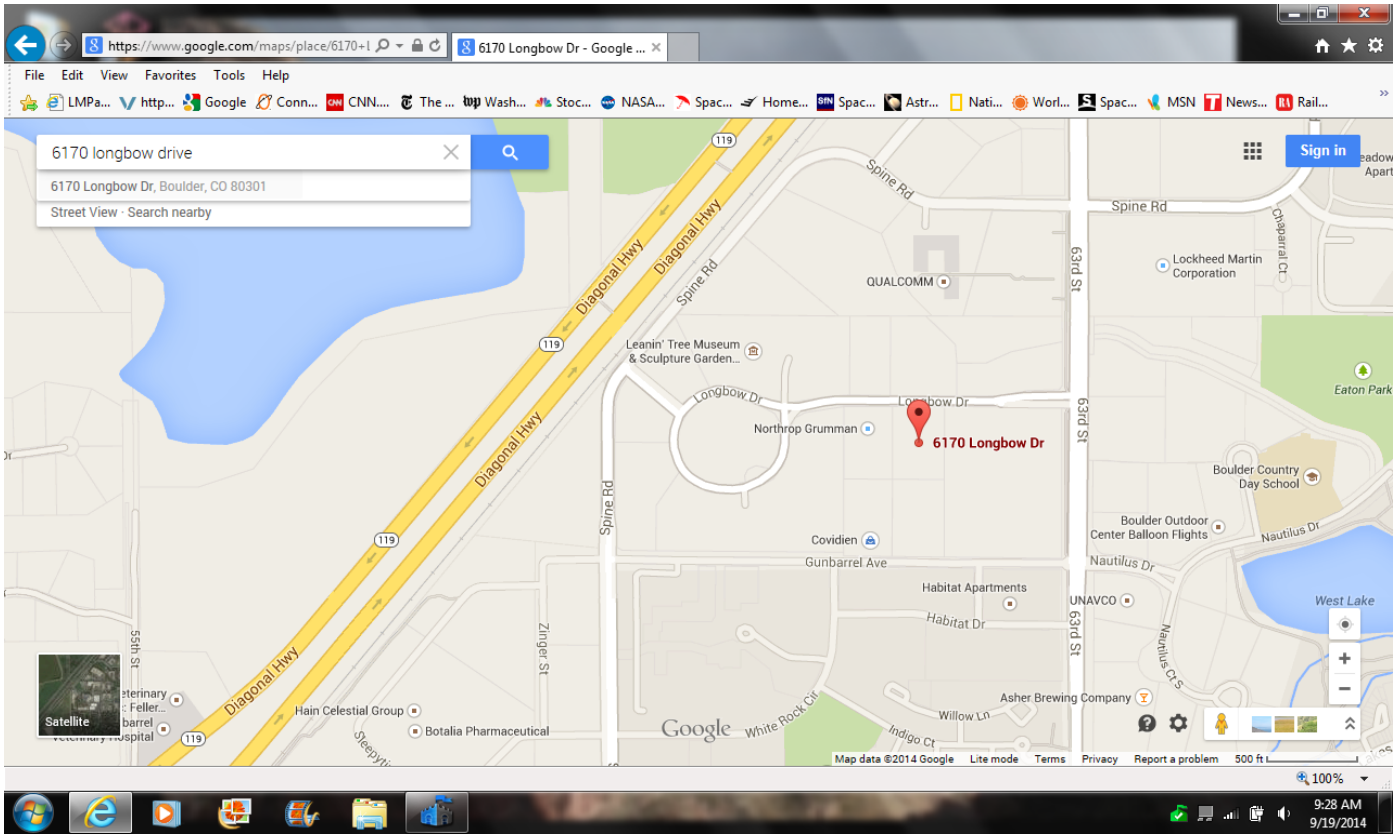
Celebrate the 25th anniversary of ISO 9000 with this exclusive bundle of resources. This bundle includes:

- Introduction to the ISO 9000 Standards Webcast
- Example Quality Manual
- New ASQ Ask the Experts Blog
- Bonus: ISO 9001:2008 Explained Webinar

Download your gift today!

Upcoming ASQ Boulder Section Meetings

Sept 25th Presenter is: Dr. Tim Rodgers, PhD Ind Engr, Ft Collins, CO speaking on: ***"Outsourcing Quality".*** The meeting will be held at the Covidien / Boulder Campus at Building #2 east-side entrance of 6170 Longbow Drive, in "Boulder Training Room", **doors open at 5:30pm.** Please see the GoogleMap below, and see the caption below the map.



Note: If you have not been to the Covidien Campus before, we suggest that you arrive 15-20 minutes early to find the meeting building and room and check-in.
Directions: On Hwy 119 between Boulder and Longmont: From Hwy 119 turn South on 63rd Street. Go ½ mile south on 63rd. Turn right (west) on to Longbow Drive. You are now in the map (above) area. Parking is On the east side of the building.

- The October meeting will be held on Oct 30th at the Settembre Cellars at 1501 Lee Hill #16 Boulder, CO 80304.
- The November meeting will be held on the 20th at the IHOP at 2040 Ken Pratt Boulevard in Longmont. The speaker will be Gary Vansuch from the Colorado Department of Transportation. The exact topic as of this writing is TBD.

RMPEx Rocky Mountain Performance Excellence Program *(which is also the Colorado State Quality and Business Performance Program),* please see page 18 of this newsletter for the most recent information on upcoming 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 pharmaceutical industries. Membership is free of charge. And, our societies' RUs' are reciprocal and interchangeable.

News continued from page 1

ASQ National –and- Local ASQ Sections' News

BOULDER SECTION CORRESPONDENCE ADDRESS

ASQ Boulder Section
P.O. Box 3783
Boulder, CO 80307 **the section website is at: http://asqBoulder.org**

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

Updates to ASQ Recertification Journal & ASQ Costs Increase in 2014

There are recent 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 remains the same. The new journal can be downloaded and printed directly from the main ASQ National website at: www.asq.org using "Certification Link" or call ASQ Customer Care at: **1-800-248-1946** and request item **B0525**

The cost of recertification recently increased due to higher costs to administer the program. This is the first cost increase in six years. Recertification by journal for members is now **$69 for one certification** or **$89 for two or more certifications** (e.g., if you get recertified for three areas or more, you pay $89).

Anyone doing a re-certification journal through ASQ Boulder Section is strongly urged to send an e-mail to the Re-cert Chair, Gerry Naugle, *BEFORE* starting your journal effort, at: gnaugle@earthlink.net. There are new streamlined policies & procedures implemented which can save you *time, effort and postage*.

Boulder Section's Current ASQ Fellows

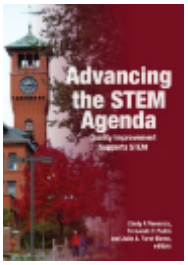
Tripp Martin – Retired
International Auto Oversight Bureau
(248) 535-5670
trippm1@earthlink.net

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

New 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).

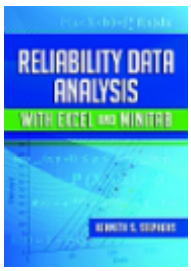
The primary audience for this book is the individual who plans to prepare to sit for the Six Sigma Master Black Belt certification examination. The book is great for quick reference and ease of use because the chapter and section numbering exactly mirrors that of the Master Black Belt BoK

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. Borror, 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.

Article on ASQ Recertification by Rebecca Jessep, ASQ Boulder Section

ASQ certification is a formal recognition by ASQ that an individual has demonstrated a proficiency within, and comprehension of, a specific body of knowledge. Nearly 150,000 certifications have been issued to dedicated professionals worldwide. An authentic professional certification is formal recognition by a respected, recognized, and established professional organization that an individual has demonstrated a proficiency within, and comprehension of, a specified body of knowledge. An ASQ certification, like most authentic professional certifications, requires that individuals demonstrate these competencies by passing an exam and having a track record of expertise in one of the specified quality disciplines, such as Six Sigma. ASQ does not require you to take the ASQ training—or any other particular courses—as a condition of awarding such certifications.

There has been a great deal of confusion as to the true meaning of certification, especially recently, as individuals and companies strive to achieve and validate competencies in a competitive job market. Numerous training companies, educational institutions, and even individual training consultants are competing to sell training courses that purportedly include "certification." In many cases, these are not certifications based on a noncommercial standard body of knowledge as developed by objective third-party entities, but rather paper certificates awarded for participating in specific training. While there is nothing wrong with providing evidence

of a course completion (whether through a document and/or accredited continuing education units), this should not be confused with the rigor and achievement of a professional certification. ASQ offers 17 certifications. These range from Calibration Technician to Certified Quality or Reliability Engineering to Manager of Quality / Organizational Excellence. Full details on certifications can be found at:
http://prdweb.asq.org/certification/control/right-for-you

ASQ requires that you recertify the following certifications every three years to ensure that you maintain the same level of knowledge demonstrated in your first exam.

- Biomedical Auditor
- Calibration Technician
- HACCP Auditor
- Manager of Quality/Organizational Excellence
- Master Black Belt
- Pharmaceutical GMP Professional
- Quality Auditor
- Quality Engineer
- Reliability Engineer
- Software Quality Engineer
- Six Sigma Black Belt
- ASQ/DON Lean Six Sigma Black Belt
-

NOTE: The Quality Inspector, Quality Improvement Associate, Quality Process Analyst, Quality Technician and Six Sigma Green Belt are "lifetime certifications". They have no re-certification requirements.

There are two ways to recertify. First, you may retake the examination. Second, you can obtain 18 recertification units (RUs) within your three-year certification period and completion of your recertification journal. The recertification journal may be found at:
http://prdweb.asq.org/certification/control/recertification/rucredits/index

ASQ Section 1313's recertification chair is Gerry Naugle. Suggest to call at: 303-591-2830 or write him at: gnaugle@earthlink.net *before you start* your next re-cert journal as he has some options which may save you time, effort and postage. More information and forms on certification, and re-certification at: www.asq.org

---

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, John Beachman at: john.beachman@covidien.com or 303-530-6346 to see if the class you want can be made available in the Colorado Springs, Denver, Loveland or Ft. Collins area.

2014 ASQ Boulder Section Course Offerings

Updated 09-20-2014

ASQ Section 1313 Education c/o Ms. Patricia Fleenor Biomet-Spine Corp. 310 Interlocken Pkwy #120 Broomfield, CO 80021

Course Name	Instructor	Course Fee (1) (2)	Exam Date	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	Dec 6th, 2014	Sept	TBD	TBD
1305 - Certified Software Quality Engineer (CSQE) Review	Arnold Miller 303-466-2631 Location: TBD	$400 members / $450 others	Dec 6th, 2014	Sept	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	Dec 6th, 2014	Sept	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	Dec 6th, 2014	Sept	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	Dec 6th, 2014	Sept	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. Contact the Boulder Education Chair, Patricia Fleenor, at:: Patricia.Fleenor@biomet.com **http://asqBoulder.org courses** If there is a class you need but is not listed above. We may be able to offer that class in the future.

COURSE REGISTRATION INFORMATION

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

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

ASQ #1313 COURSE REGISTRATION FORM

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

Student's Name: _____ ASQ Membership #:_____

or other Society and #: _____

Title: _____

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 Patricia Fleenor, at: **patricia.fleenor@biomet.com** (or) 303-501-8457, to reserve your spot in the course that you want. Please send checks to the address below.

ASQ Section 1313 Education c/o Ms. Patricia Fleenor Biomet-Spine Corp. 310 Interlocken Pkwy #120 Broomfield, CO 80021

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

If you are seeking ASQ certifications I do exam preparation classes for most certifications such as:

- **Certified Manager of Quality/Organizational Excellence (CMQ//OE)**
- **Certified Reliability Engineer (CRE)**
- **Certified Six Sigma Black Belt (CSSBB)**
- **Certified Quality Engineer (CQE)**
- **Certified Quality Auditor (CQA)**
- **Certified Six Sigma Green Belt (CSSGB)**

I offer public seminars only if the demand is there. All my training can be offered "in-house". In-house training is more cost effective if you have 6 or more trainees. I recommend you start the preparation process at least 3 months prior to any exam.

IMMEDIATE ATTENTION -- The next exam date will be December 6th (CQE, CQA, CSSGB). Preparation for these exams should begin no later than September. In these tough economic times, I am willing to give individuals advice on exam preparation. This is a free service.

Classes and Seminars

Many of the following are helpful for those seeking ASQ certification and/or implementing an effective quality system. ISO 9001:2015 Revision, Applied Statistics, Process-Based Auditing, Service Quality, The Tools of Quality If the you have a specific quality need, I can customize a training class to meet that need.

Ron Sedlock the quality Catalyst
phone: 303.716.5873 or 303.587.9153 (cell)
www.thequalitycatalyst.com

Colorado Quality Executive Network (CQEN)

Colorado Quality Executive Network (CQEN) http://www.thequalitycatalyst.com
Date: Thursday, October 16, 2014
Time: 1:00 to 5:00 pm
Location: Coors Brewery, Golden Topic: Cost of Quality
The Colorado Quality Executive Network (CQEN) is a network of people who have the top quality responsibility at organizations. The purpose of the network is to share ideas on what works and doesn't work in the pursuit of quality at the executive level.
Participation in this network is by invitation only. Please contact Ron Sedlock if you have an interest.
Ron Sedlock phone: 303.716.5873 or 303.587.9153 (cell)
Email: ronsedlock@thequalitycatalyst.com

Rocky Mountain Regulatory Affairs Society presents *Process Validation for Medical Devices*
Friday, October 3, 2014 8:00 am – 5:00 pm

This one-day Process Validation workshop intends to help make process validation a useful activity, with payback and not just cost. The presenters believe value-added process validation requires cross-functional interactions and aim to foster discussion among attendees at various levels of expertise, and in different positions within their firm's organization chart. The workshop will include information, discussion, and case studies based on the following questions:

Why validate? When to verify? · Does design control impact process validation? How does validation and verification relate to risk? What is needed to document validation? Can we justify the cost of process validation?

FACULTY: **Neil Burris - CBA, RAC, RM (AAM)** Neil Burris entered the medical device business in 1988, working for a manufacturer of implantable cardiac pacemakers. Mr. Burris' various experiences in Quality Systems, Contamination Control, Clinical Data Management, and Sterilization Science combine to form a background particularly suitable for understanding regulatory affairs for medical devices. He strives to aid in facilitating the legal sale of ethical, safe, and effective devices. He has previously served on standards writing committees for the Association for the Advancement of Medical Instrumentation (AAMI) and the Institute for Environmental Sciences and Technology (IEST). He currently serves on the Steering Committee Rocky Mountain Regulatory Affairs Society and earns a living via a successful independent consulting practice. Mr. Burris was formally educated at Colorado State University and holds degrees Chemistry and Microbiology. He is a Certified Biomedical Auditor, Regulatory Affairs Certified, and a Registered Microbiologist

Adrian Elfe - QM/OE, ASQ Fellow Mr. Elfe serves as Principle Consultant of Elfe Consulting assisting organizations in meeting their start up, validation, auditing, documentation, regulatory compliance, regulatory submissions, process improvement, lean improvement and quality system needs. Adrian retired in July, 2007 after seventeen years as a Corporate Executive with the Spectranetics Corporation, a medical device manufacturer. He served as Vice President of Quality Assurance and Regulatory Affairs as well as a corporate officer. Adrian has been responsible for quality, general management, regulatory system development, implementation and compliance. He has been responsible for Quality / Regulatory System planning and implementation for fourteen different spin off/startup businesses in three different FDA Districts - all which have been successful. He has over With over 40 years of experience in the medical device Industry, he has worked in domestic and foreign regulatory compliance, microbiological QA, new product development, product introduction and manufacturing facilities start up, integration and relocation. He has a technical background in Electrical Engineering, Management Systems and Manufacturing Technologies. He is a Certified Quality Manager.

LOCATION: Springhill Suites Downtown Denver, 1190 Auraria Parkway, Denver, CO 80204. Phone: 303-705-7300. Parking at the hotel is $20/day; at the Tivoli $6/day

COST -

$345.00 - EARLY BIRD DISCOUNT - SIGN UP BEFORE SEPT 3 AND SAVE $50.00

$395.00 – Cost after September 3

The regular cost for the workshop is $395.00, which includes all course materials, continental breakfast and lunch. To register, please go to **www.regonline.com/procvalidation** **BE AWARE THAT THIS COURSE IS LIMITED TO 50 REGISTRANTS** For additional details or information, contact Nan Matthews, programs@rmras.org or 303-843-6414.

Quality-Related Career Openings / New Job Postings

COVIDIEN
positive results for life

Job Title: **Sr Software Design Quality Engineer**

Job ID Number: **140003KA** **Locations:** ***United States*** **- Boulder, CO**

Job Description

Design and deliver the medical device and supplies breakthroughs that make a difference in the lives of millions of patients.

The Senior Software Design Quality Engineer ensures that software used in the development, manufacturing and as part of medical devices is developed according to good design practices and follows the corresponding

requirements set forth by local procedures, regulatory authorities and notified bodies. Provide leadership, oversight and training to division manufacturing plants forsoftware design quality. Mentor design teams on quality systems and requirements.

What is the work you will be doing? Create a risk management plan, perform product risk assessment, facilitate the failure mode effects analysis, and create a final risk management report
Promote a structured software development process. Assure that control is maintained for in-house and outsourced software development. Ensure compliance with internal and external procedures and regulations. Participate in review of requirements, architecture, design, code and other work products with a focus on patient safety and device quality, testability, manufacturability and serviceability. Participate in change review meetings for product and non-product software.
Provide oversight of manufacturing software validation process.

Generate metrics for assessing software quality and evaluate results. Contribute to process improvements by developing and/or updating written company or departmental procedures related to software development. Provide oversight during software release to manufacturing as well internal distribution. Administer and control problem-tracking database and oversee defect process resolution. Support outsourced software vendor audits and qualification. Ensure that new product development and changes to existing products are conducted in compliance with the FDA Quality System Regulations and Covidien internal processes.

Oversee analysis for standards and product requirements compliance.
Provide guidance and direction for sample size and statistical analysis of verification and validation test results. Provide training to project teams on procedures,statistical methods and design controls. Review Design History Files and Technical Files for conformance to applicable requirements Assist, when appropriate with internal and supplier audits. Provide Quality support to facilitate the rapid resolution of product complaints and/or safety issues.

Qualifications
Do you have these experiences or skills?
Required:
5+ years of software design quality / compliance engineering experience or equivalent
Working knowledge ofC++
Working knowledge of the FDA Quality System Regulation, ISO 13485, and the Medical Device Directive
Skilled in product risk assessment (ISO 14971), requirements management and tracing, defect tracking, configuration management techniques, and knowledge of how these are applied in the software development lifecycle

Understanding of current Software Quality techniques, software industry standards (e.g. ISO, IEEE, CMMI), and FDA Quality System Regulations and their impact on internal procedures, software quality, safety and efficacy of products
Good verbal (including presentation) and written communication skills

Experience with standards for the design, verification, and validation of medical device products with emphasis around software development.
Ability to effectively work on project teams.

Preferred: **Understanding of Object Oriented programming techniques. Working knowledge of Unified Model Language (UML) ASQ CQE, CRE or CSQE certification**
Strong familiarity with regulatory requirements (e.g. ISO 62304, ISO 13485, 21 CFR Part 11, 21 CFR 820, ISO 14971). Experience in risk evaluation techniques, such as PRA (Product Risk Assessment), FMEA & fault tree analysis. Familiar with reliability analysis and test methods, including HALT and HASS.

Skilled in statistical methods, including ANOVA, statistical process control, sampling plans, gauge R&R, and design of experiments. Do you have these academic certifications? Bachelor of Science degree in Software Engineering, Computer Science, Computer Engineering or Electrical Engineering
.
Working Conditions Normal office working conditions.
Some travel required. Call 303-530-2300 ask for H-R Department Representative

Cardinal Health, Denver is seeking a temporary 12 month contract position as Quality Engineer located at the Denver, CO office.

Job Duties:

- Review and approve product specifications, design control documentation, and manufacturability as a team member of the design team.
- Recommend, acquire and validate the necessary tools, equipment and technologies to support inspection and testing activities.
- Leads Material Review Board to analyze, investigate, disposition, and resolve discrepant product.
- Coordinate supplier interactions for manufacturing and nonconforming material.
- Leads Corrective and Preventive Action and Complaint activities.
- Guide the risk management process, leading risk assessment team and compiling risk management reports.
- Develop quality plans, quality criteria, and inspection techniques to monitor the finished device from contract manufacturers.
- Manage supplier validation activities including supplier assessment, protocol development, and generation of supplier validation master plan(s).
- Evaluates customer returns and feedback; communicates results effectively with the customer.
- Assists in design validation activities, and facilitates process validation activities.
- Assists design team in gage development.
- Supports the Quality Department in maintaining a compliant quality system.
- Work on continuous improvement activities. These may include participating in, and/or leading Quality Improvement Teams.
- Provide quality reports and review trending on assigned areas of responsibility.
- Provides training to employees on quality system elements.
- Other duties as assigned

Qualifications:

- More than 5 years experience in the Medical Device industry
- Bachelors of Science Degree, Engineering degree preferred.
- Fluent in ISO 13485:2003 and 21 CFR 820.
- Geometric Dimensioning and Tolerancing (GD&T) knowledge.
- Ability to assess priorities in a dynamic, fast-paced work environment.
- Work independently with minimal supervision and increasing responsibility.
- Demonstrated attention to detail and organizational skills
- Ability to build relationships between Quality Assurance and other areas of the organization

---

SYNERGY HEALTH Director of Quality Assurance

and Regulatory Affairs

SUMMARY: The Director of Quality Assurance and

Regulatory Affairs oversees the quality assurance

departmentof Synergy Health AST, Americas division to

assure compliance to the quality system and all applicable

standards.

ESSENTIAL FUNCTIONS:

- Establishes procedures for maintaining high standards of service, quality, reliability, and safety.
- Determine and enforce – through functional groups – quality and regulatory requirements in accordance with company needs, based on current regulations and state-of-the-art product development.
- Organize and promote companywide quality and service improvement efforts.
- Implement and maintain the company quality system within AST network, report on the performance of the quality system for review and as a basis for improvement of the quality system.
- Support sites with quality related and/or customer issues that cannot be reconciled at the site level.
- Assure the adoption of the Synergy Health company quality system at each new service center.
- Act as liaison with external parties on matters pertaining to the quality system.
- Assure Synergy Health compliance to ISO/AAMI/ANSI/ASTM/CFR standards.
- Assure the implementation and training of GMP/QSReg and ISO requirements.
- Act as the primary Management Representative for Synergy Health AST business segment.
- Co-lead the Quality Assurance managers for each service center.
- Act as quality expert for Synergy Health AST customers.
- Track and maintain the KPIs for all AST Americas sites
- Perform special projects and assignments as requested by management.
- Serve as the primary Synergy Health representative and liaison with local, county, state, and federal personnel to ensure permits and compliance monitoring systems are implemented and maintained for both existing and new facilities.

Synergy Health is a service company that requires that you are always providing some level of service to either an internal or external customer. You are expected to make decisions that will in effect, positively impact and exceed the expectations of the customer base you serve. Accuracy, delivering on our commitments and the manner in which we execute each transaction must be done in such a manner that it positively spreads our organization's reputation. Although we cannot always choose the specific work assigned to us, we can however determine the attitude, behavior and personality we portray in completing our work.

SUPERVISORY RESPONSIBILITIES:

Via matrix management, co-supervise the Quality Assurance Department of Synergy Health consisting of Service Facility Quality Assurance managers. Directly supervises the AST Corporate Quality Manager and Software Quality Engineer.

WORKING CONDITIONS:
Work is generally performed in a standard office environment with little or no exposure to excessive noise, dust, temperature, etc. Whenever traveling to a facility the position entails exposure to a warehouse environment, including moderate temperature to excessive heat, moisture, chemicals and noise.

EXPERIENCE:
A minimum of 7 years of related experience with FDA registered companies is desired, with at least 2 years in quality management role.

EDUCATION: Bachelor Degree in a technical discipline is preferred; with additional classwork in management-related courses and problem-solving techniques (i.e. Statistical Quality Control/Statistical Process Control).

KNOWLEDGE, SKILLS, ABILITIES: Excellent verbal, written communication and mathematical skills required. Must be a team player.

- Strong computer skills required, excellent working knowledge of MS Word, MS Excel. Experience with Synergy Health's current operating software preferred.
- Ability to present and execute regulatory and quality programs working closely with senior management and facility personnel.
- Able to interpret technical data to ensure integrity of quality systems and/or processes.
- Self-starter, flexible, detailed oriented individual with the ability to work independently when required. Ability to set priorities and effectively manage/coordinate multiple projects while maintaining timelines.
- Desire to be a quality process orientation champion.
- Ability to understand, interpret, implement and communicate Synergy Health, FDA and other regulatory agencies' GMP/ quality requirements.

Experience in problem solving and root cause analysis. Ability to make decisions on imperfect information, with a bias towards collaboration with key stakeholders, balanced with action and decisiveness. Agility and multi-tasking capabilities. Lean Six Sigma experience preferred.
TRAVEL REQUIRED: Approximately 50% SYNERGY HEALTH IS AN EQUAL EMPLOYMENT OPPORTUNITY/AFFIRMATIVE ACTION EMPLOYER –
M/F/V/D.

To apply, please go to https://synergyhealthplc.applicantpro.com/jobs/138511.html

---

Baxter

A global diversified healthcare company and industry leader

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified

healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide. Baxter had 2013 sales of $15.3 billion and has ~ 61,500 employees.

A career with a higher purpose

If you have a desire to learn, grow and innovate, you can find purpose and satisfaction at Baxter, and make a contribution to a greater good. Whether you're interested in medical devices, pharmaceuticals or biotechnology – or all three – Baxter offers the opportunity to explore the path that's right for you. Our combined expertise in these three areas is unique and it differentiates us from other companies in the healthcare industry.

Our employees around the world are connected by an enduring commitment to save and sustain lives. It's this higher purpose that binds us as a company and as global citizens.

Discover how you can join Baxter and work in an innovative and exciting place while helping make a meaningful difference for millions of people around the world. Learn more.

Equal Employment Opportunity

Discrimination in hiring, promotion and all other employment decisions on the basis of race, color, religion, gender, national origin, age, disability, sexual orientation, gender identity or expression, protected veteran status, disability/handicap status or any other basis protected by Federal, state or local laws is prohibited. Puerto Rico laws also prohibit discrimination based on social and political ideas.

As a federal contractor, Baxter is also subject to Executive Order 11246. In addition to prohibiting discrimination, this Executive Order also requires Baxter to be an Affirmative Action employer. Baxter is committed to working with and providing reasonable accommodation to individuals with disabilities.

Open Role – Senior Engineer (Quality Engineering)

The **Senior Engineer (Quality Engineering)** provides technical support, guidance and project leadership to the Software Quality Engineering Center of Excellence (COE) with emphasis on Software Quality Assurance, Design Controls, and other areas of Quality System Regulatory Compliance.

Essential Functions:

- Manages and performs product and process Validation and Verification activities. Demonstrates commitment to project team results and assists other team members in meeting their goals. Contributes to project planning process. Act as the Voice of Quality on cross functional teams.
- Has a thorough understanding of product and process validation, Test Method Validation, measurement capability analysis, and failure analysis.
- Interprets data and provides judgment to influence decisions. Effectively communicates complex information throughout organization, both verbally and in writing.
- Experience in evaluating risk through formal risk analysis, PFMEA, FMEA, fault tree analysis, and other recognized tools.

- Act as a liaison between new product development and production implementation.
- Provides leadership and guidance in the area of Quality Control.
- Authors Quality System procedures used to run the company.
- Evaluates, selects, and applies standard engineering practices.

Knowledge, Skill and Ability:

- Experience with validation, lean systems and continuous improvement methods
- Understanding of regulatory based quality systems
- Display a solid technical understanding of engineering principles and procedures
- Understand and articulate how own role ties within function or discipline
- Demonstration application of engineering principles on individual/small projects
- Background and/or Experience: BS engineering and 3-5 years related experience.

Education or Formal Training: BS Engineering

Experience: 3-5 years related experience

To apply for this role, please visit the Baxter Career Site at:
http://www.careers.baxter.com/us/index.html

Baxter

A global diversified healthcare company and industry leader

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.
Baxter had 2013 sales of $15.3 billion and has ~ 61,500 employees.

A career with a higher purpose

If you have a desire to learn, grow and innovate, you can find purpose and satisfaction at Baxter, and make a contribution to a greater good. Whether you're interested in medical devices, pharmaceuticals or biotechnology – or all three – Baxter offers the opportunity to explore the path that's right for you. Our combined expertise in these three areas is unique and it differentiates us from other companies in the healthcare industry.

Our employees around the world are connected by an enduring commitment to save and sustain lives. It's this higher purpose that binds us as a company and as global citizens.

Discover how you can join Baxter and work in an innovative and exciting place while helping make a meaningful difference for millions of people around the world. Learn more.

Equal Employment Opportunity

Discrimination in hiring, promotion and all other employment decisions on the basis of race, color, religion, gender, national origin, age, disability, sexual orientation, gender identity or expression, protected veteran status, disability/handicap status or any other basis protected by Federal, state or local laws is prohibited. Puerto Rico laws also prohibit discrimination based on social and political ideas. As a federal contractor, Baxter is also subject to Executive Order 11246. In addition to prohibiting discrimination, this Executive Order also requires Baxter to be an Affirmative Action employer. Baxter is committed to working with and providing reasonable accommodation to individuals with disabilities.

Open Role – Senior Engineer (Software Quality Engineering)

The **Senior Engineer (Software Quality Engineering)** provides technical support, guidance and project leadership to the Software Quality Engineering Center of Excellence (COE) with emphasis on Software Quality Assurance, Design Controls, and other areas of Quality System Regulatory Compliance.

Essential Functions:

- Ensures that software/computer system implementation meets the requirements for validation.
- Trends and reports test coverage and execution metrics.
- Trends and reports defect discovery and closure rates in support of quality improvement initiatives.
- Identify and contribute to quality improvement initiative efforts.

Duties/Responsibilities to accomplish Essential Functions:

Specific responsibilities may include, but are not limited to:

- Execute best practices for SQE test infrastructure.
- Lead Software Test Execution initiatives.
- Understand FDA Design Controls and their application to Baxter Product Development.
- Monitor/Review/Manage test development and execution to ensure compliance with FDA quality system regulations.
- Communicate with internal and external customers regarding requirements, functionality and other design expectations.
- Act as the voice of Software Quality on cross functional teams.
- Documenting methodology and results according to regulatory and company expectations

Knowledge, Skill and Ability:

- Knowledge of standard SQA methodologies and practices, and their application
- Strong understanding of software/SDLC methodologies and tradeoffs between approaches
- Understanding of software/system configuration management and change control
- Excellent verbal and written communication skills
- Proficient PC skills and the ability to apply these tools to data analysis
- Ability to plan and design testing scripts
- Proficient with Object Oriented programming languages

Education or Formal Training:

- BS in Engineering Discipline

Experience:

- Minimum of three years of experience in Software Quality Assurance **To apply for this role, please visit the Baxter Career Site at: http://www.careers.baxter.com/us/index.html**

Quest for Excellence 2014 Denver Marriot SE

Kim Griffiths and Doug Gilbert get us started at the 2014 RMPEx Quest for Excellence.

Peak Recipient:

Elevations Credit Union

Pete Reicks accepts the Peak Award for Elevations Credit Union

Elevations Group at 2014 Quest

Timberline Recipients:

AlloSource

Donna Sinn accepts the AlloSource Timberline Award.

AlloSource Group at 2014 Quest

City of Fort Collins

Fort Collins attendees at the 2014 Quest.

Maureen Tarrant accepts the Sky Ridge Medical Center Timberline Award.

Sky Ridge Medical Center Quest attendees.

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

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

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