MAY 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. This defines the future state. The current state is how things are now. 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. Can you detect a shift towards the future state? How much of an improvement was needed? (Remember the Planning step? Part of planning needs to be defining how much of an improvement is needed in the 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 performing 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

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May 2014

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 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

Emerging Quality Leader Program Site Now Available

Registration for the inaugural class of the ASQ Emerging Quality Leaders Program (EQLP) is now available through the EQLP website, www.emergingqualityleaders.org. If you or someone you know is interested in unique networking opportunities, visiting Fortune 500 companies, or obtaining a top-quality executive mentor, take advantage of this exciting opportunity! Applications are being accepted for the 2014 class.

News continued on page 5
### ASQ #1313 Officers & Committee Chairs 2014

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<th>Boulder, CO</th>
</tr>
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<tr>
<td><strong>Title:</strong> Chair</td>
<td><strong>Name:</strong> Joe Wojniak</td>
</tr>
<tr>
<td><strong>Phone:</strong> 303-530-6581 <a href="mailto:Joe.wojniak@gmail.com">Joe.wojniak@gmail.com</a></td>
<td></td>
</tr>
<tr>
<td><strong>Title:</strong> Vice Chair</td>
<td><strong>Name:</strong> Position Open</td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td></td>
</tr>
</tbody>
</table>

| **Title:** Secretary | **Name:** Patricia Fleenor |
| **Phone:** 303-501-8457 patricia.fleenor@biomet.com |
| **Title:** Treasurer  | **Name:** John Beachman  |
| **Phone:** 720-313-2746 john.beachman@coviden.com |

| **Title:** Re-Cert | **Name:** Gerry Naugle |
| **Phone:** 303-591-2830 gnaugle@earthlink.net |
| **Title:** Internet & Website | **Name:** Arnold Miller  |
| **Phone:** 303-868-4807 arnold.miller0@gmail.com |

| **Title:** Publicity and VOC | **Name:** Byron Murray |
| **Phone:** 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 |

### 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!

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### Advertise in the ASQ Boulder Section e-newsletter in 2014-15!

Effectively get your company’s information out in front of Boulder, Broomfield and Denver County QA Professionals.

**Rates are………………..**

- $20 for a 1/4 page one issue (and) $30 for a 1/2 page for one issue
- $60 for a 1/4 page for all eight issues in a year from the start (and)
- $80 for a 1/2 page for all eight issues in a year from the start

Contact Gerry Naugle at: gnaugle@earthlink.net (or) 303-591-2830
Upcoming ASQ Boulder Section Meeting

May 22nd    Doors open at 5:30pm at: Biomet – Spine Corp located in Broomfield/Interlocken    310 Interlocken Pkwy #120 in 80021 (for GPS)

5:30 pm: Networking and refreshments served
~ 6:05 PM  Co-Presenters Kathleen Newberg from State of Colorado (and) Patrice Hawkins of the City and County of Denver

Abstract: Colorado State Government Using Lean: An overview of how the Colorado Department of Health Care Policy and Financing (HCPF) is creating culture change through the rollout and use of Lean. Discussion of successes, challenges and lessons learned during the first two years of Lean implementation.  Ms. Kathleen Newberg - LEAN Leader,  kathleen.newberg@state.co.us  Similar presentation theme by Ms. Patrice Hawkins of the City and County of Denver | Associate Process Improvement Analyst Budget & Management Office,  Patrice.Hawkins@denvergov.org

Attendee RSVP requested by 21May at 3:00pm. Please contact Dan Clark at: 720-326-8240 (or) dpclark@live.com  to RSVP.  Please see map below to Biomet-Spine Corp, it is where the Red A is located.

If you have not been to Biomet-Spine Corp previously, we suggest that you plan to arrive in the Interlocken-area about 15 min early to ensure finding the Biomet Building successfully.

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Rocky Mountain Performance Excellence Program (which is also the Colorado State Quality and Business Performance Program), please see page 17 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.

**RMRAS** Rocky Mountain Regulatory Affairs Society [http://rmras.org/](http://rmras.org/) The RMRAS is the premier professional society in Denver-front range area for individuals involved in medical device or pharmaceutical industries. Membership is free of charge. Our societies’ RU’s are reciprocal and interchangeable.

News continued from page 1

**ASQ National  and Local ASQ Sections’ News**

**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.

Updates to ASQ Recertification Journal
ASQ Recertification 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, 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 & procedure implemented which can save you time, effort and postage.

Boulder Section – Current ASQ Fellows

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

Ed 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

BOULDER SECTION CORRESPONDENCE ADDRESS
ASQ Boulder Section
P.O. Box 3783
Boulder, CO 80307
website is:  http://asqBoulder.org

Note: All education & course registration materials should be sent to Section Education Chair (please see the last page of the education section for contact information)
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 him at: 303-591-2830 or write him at: gnaugle@earthlink.net before you start your 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
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 04-14-2014

<table>
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<tr>
<th>Course Name</th>
<th>Instructor</th>
<th>Course Fee (1)</th>
<th>Exam Date</th>
<th>ASQ Exam Application Deadline</th>
<th>Course Dates &amp; Times</th>
<th>Course Registration Deadline</th>
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<tr>
<td>1301 - Certified Quality Engineer (CQE) Review</td>
<td>Monrad Monsen 303-272-9612 Location: Contact Instructor</td>
<td>$400 members / $450 others</td>
<td>June 7, 2014</td>
<td>April 18, 2014 April 23 (late)</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>1305 - Certified Software Quality Engineer (CSQE) Review</td>
<td>Arnold Miller 303-868-4807 Location: TBD</td>
<td>$400 members / $450 others</td>
<td>June 7, 2014</td>
<td>April 18, 2014 April 23 (late)</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>1322 - ASQ Exam BoK: Quality Concepts, Management and Leadership</td>
<td>Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD</td>
<td>$270 per student + $25 material = $295 Total</td>
<td></td>
<td></td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>1323 - ASQ Exam BoK: Statistical Principles, Techniques and Applications</td>
<td>Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD</td>
<td>$270 per student + $25 material = $295 Total</td>
<td></td>
<td></td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>1324 - ASQ CQE Book of Knowledge (Bok) Review</td>
<td>Ron Sedlock 303-716-5873 or 303-587-9153 Location: TBD</td>
<td>$135 per student + $15 material = $150 Total</td>
<td></td>
<td></td>
<td>TBD</td>
<td>TBD</td>
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</table>

(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, John Beachman, for details. FOR INFORMATION UPDATES please go to the Boulder Section web page: http://www.asq1313.org/courses.html

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](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](mailto: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 have any quality training needs, keep me in mind. I offer a variety of quality classes such as:

- Effective Quality Management Systems
- Lean Six Sigma Statistics
- ISO 9001 Process-Based Auditing
- Baldrige Criteria Assessments
- Service Quality
  Many of the classes are helpful for those seeking ASQ certification and/or implementing Lean Six Sigma improvement. If you have a specific quality need, I can customize a training class to meet that need.

If you are seeking ASQ certifications I do exam preparation classes for most certifications. I recommend starting preparing at least 3 months prior to any exam. For the following June 7th exams you should start in March:

- 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.

If you are planning to study alone for a certification exam, I can give you advice on the best way to prepare. This is a free service.

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
- Meeting: 2014 July 17 (Thur) 1:00pm to 5:00pm
- Topic: Customer Satisfaction
- Speaker: Round table
- Place: Quantum, Englewood

Group Information and Contact Information
- 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

The Rocky Mountain Regulator Affairs Society is proud to be a co-sponsor of a Drug and Device Conference from the Association of Food and Drug Officials (AFDO). The conference will be in Denver June 22 – 25, 2014 and will also include food track.

Topics include: UDI Implementation Quality Agreements

- 9 -
Compounding Pharmacies  Device Recalls  Comparison of US/EU Device Regulations
Pharmaceutical Inspections  Case for Quality Updates  Biosimilars Regulations
Q&A with FDA  FSMA Topics  Emerging Risks of a Global Food System

The cost for the entire conference is $575.00. To register visit [http://denver.afdo.org/register.html](http://denver.afdo.org/register.html)

We hope that you will join us for this event. Please forward to your colleagues that may be interested.

Drugs and Medical Devices Seminar  “Promoting Public Health, Fostering Uniformity, and Establishing Partnerships”

Association of Food and Drug Officials (AFDO)
Drugs & Medical Devices Seminar
Co-Hosted by the Western Association of Food and Drug Officials
Co-sponsored by the U.S. Food and Drug Administration & Rocky Mountain Regulatory Affairs Society  June 23-24, 2014
Grand Hyatt Denver, Denver, Colorado

FDA and Global Engagement: Progress on the Pathway to Global Product Safety. This seminar will primarily be attended by industry representatives from the pharmaceutical and medical device community as well as federal and state regulatory officials. Topics for discussion include the following: Medical Device Single Audit Program, Contract Manufacturing Arrangements for Drugs, Compliance Question Panel featuring Key FDA Representatives, Medical Device Recalls, Compounding Pharmacies, Comparison of EU and US Device GMP Requirements, UDI Implementation, Pharmaceutical Inspection Co-operation Scheme, and Biosimilars Regulations.

For more information visit: [http://denver.afdo.org/](http://denver.afdo.org/)

AFDO is an international non-profit organization devoted to developing strategies to resolve and promote public health and consumer protection issues related to the regulation of foods, drugs, medical devices, and consumer products. Membership includes individuals from local, state and federal regulatory agencies, regulated industry, and academia who are concerned with the development and enforcement of uniform food, drug, and consumer product safety laws and regulations.

Cruisin'

ASQ Human Development and Leadership Division (HD&L) in conjunction with ASQ Greater Fort Worth Section 1416 is sponsoring the **ASQ 2014 Quality Cruise for Professional Development**. The cruise will set sail from Galveston, TX on October 26 for 8 days, 7 nights returning on November 2. Join us on the Royal Caribbean’s **Navigator of the Sea** and tour the Caribbean (Cozumel, Grand Cayman and Jamaica) including 3 days at sea with morning and afternoon conference activities and presentations. Cruise with family and quality colleagues for fun and learning! For More information [http://asqhdandl.org/uploads/3/3/8/3338526/qcruise_fast_fact_sheet_20140402.pdf](http://asqhdandl.org/uploads/3/3/8/3338526/qcruise_fast_fact_sheet_20140402.pdf)
Quality Related Career Openings / New Job Postings

University of Colorado: Gates Biomanufacturing Inc.

Director of Quality 

About the Company:
The Gates Biomanufacturing Facility will be established as an auxiliary service center of the University of Colorado’s School of Medicine, Department of Dermatology and the Charles C. Gates Center for Regenerative Medicine and Stem Cell Biology

Website: Gates Biomanufacturing Facility

Job Description:
The Gates Biomanufacturing Facility is seeking a qualified candidate that will be responsible for directing quality assurance and quality control (QA/QC) for the Facility. The Director of Quality will plan and establish QA/QC policies, programs, systems and initiatives. In addition, the selected candidate will establish testing methods and systems to ensure quality standards and specifications are met.

Requirements:

Examples of Work Performed
• Design, establish, and manage QA/QC policies, programs and systems.
• Review and approval of all products and materials for release.
• Participate in the preparation of CMC section for a biological product IND.
• Establish positive relationships with internal and external members of the Gates Center community as well as users of the manufacturing facility.

Knowledge, Skills, and Abilities
• Master’s Degree or equivalent experience in a life sciences discipline.
• Significant industrial experience in QA/QC.
• Strong knowledge of cGMP/cGTP regulations and industry standards.
• Familiar with the preparation and development of CMC section for a biological product IND.
• Experience with working in a biotech startup environment.
• A team-oriented, self-starter capable of operating independently.
• Effective interpersonal communication skills.

Minimum Requirements
• Master’s Degree or equivalent experience in a life sciences discipline.
• At least 10 years of industrial biotech experience in a QA/QC role.
• A team-oriented, self-starter capable of operating independently.

Preferred Qualifications
• Experience working for biotech companies is a plus.
• Experience working in a cGMP manufacturing setting is desired.

Application Information:
All applications must be submitted electronically at www.jobsatcu.com, refer to job posting RF01234. The jobsatcu.com employment board has this position listed as a Research Instructor.

Required Application Materials:
When applying at www.jobsatcu.com, applicants must include:
1) A letter of application which specifically addresses the job requirements and outlines qualifications.
2) A current CV/Resume.
3) The names, addresses, daytime telephone numbers and e-mail addresses for three professional references.

Review of applications will continue until the position is filled. Salary is commensurate with skills and experience. The University of Colorado offers a full benefits package. Information on University benefits programs, including eligibility, is located at http://www.cu.edu/pbs/.

The University of Colorado Denver is dedicated to ensuring a safe and secure environment for our faculty, staff, students and visitors. To assist in achieving that goal, we conduct background investigations for all prospective employees.

The University of Colorado strongly supports the principle of diversity. We encourage applications from women, ethnic minorities, persons with disabilities and all veterans. The University of Colorado is committed to diversity and equality in education and employment.

Please be advised that the University does check references as part of the employment process.

FreeWave Corp Quality Engineer

- Job Tracking ID: 512437-431375
- Job Type: Full-Time/Regular
- Location: Boulder, CO
- Date Updated: March 20, 2014
- Job Level: Mid Career (2+ years)
- Years of Experience: 5 - 7 Years
- Level of Education: BA/BS
- Starting Date: ASAP

Position Overview:
The Quality Engineer will be reporting to the Quality Manager and help drive key quality initiatives throughout the company. The main focus will the monitoring and closure of Quality issues internally and externally, and maintaining ISO certification in addition to improving processes by monitoring key metrics.
Work will be performed at the FreeWave Technologies location in Boulder, Colorado unless otherwise specified by functional Management.

Principal Job Functions:
To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Work cross-functionally to ensure all ISO procedures are followed and Training Guides are utilized to standardize on and improve processes.
- Initiate and manage Non Conformance Reports (NCRs) from initial problem recognition to closure based on Field / Customer, Supplier, Manufacturing / Production, and Process issues.
- Perform internal audits to ISO procedures on a regular basis to ensure compliance to the QMS procedures for all functions at FreeWave.
- Document and maintain records in ISO Database.
- Conduct customer surveys to gauge FreeWave’s performance in the eyes of customers and satisfy one of the major Quality Objectives.
- Update and revise ISO procedures and maintain in database, to improve upon processes, where deemed necessary, as a continual improvement.
- Perform assessments and audits of major component suppliers, such as suppliers of electronic modules used on FreeWave products.
- Concentrate on supplier performance and drive issues with major components to resolution.
- Prepare and support Surveillance Audits that are conducted by ISO auditors yearly.
- Provide refresh ISO training to employees in preparation for the re-certification audit and support preparation for the re-certification audit.
- Manage supplier certification surveys and approval of new suppliers and updates to existing suppliers, keeping a current list and up to date certification in the ISO database.
- Manage corrective and preventive actions to ensure Non-Conformances are addressed and closed. This task will be ongoing as Quality issues are surfaced and need to be resolved throughout the company.
- Review quality metrics and data and use statistical techniques to show trending issues for product and process improvement.
- Utilize 8D reporting method to drive corrective and preventive actions.
- Maintain Employee List in ISO database and keep current with HR training and/or certification records.
- Work with HR to ensure all employees’ training is completed, verified and up to date and records in the ISO database are up to date.
- Work with Manufacturing and Engineering to implement and update Assembly Instructions on all products.
- Other duties as assigned
- Must be a US Person in accordance with United States immigration laws to be considered for this position.
Experience and Skills:

Knowledge, Skills and Abilities:
- Four to seven year experience in developing and maintaining a Quality Management System (QMS) and supporting certification to ISO 9001/AS9100.
- Excellent written and oral communication skills are required.
- Excellent organizational skills and attention to detail are required.
- Demonstrated analytical expertise including ability to plan, resolve problems effectively, and establish priorities.
- Working knowledge of Quality Management Systems (QMS) is required.
- Internal auditing skills in ISO 9001 or others is highly desired.
- Knowledge in Printed Circuit Board and/or electronics is preferred.
- Must be a US Person in accordance with United States immigration laws to be considered for this position.
- Quality minded individual with proven records of promoting Quality as a major driver for customer satisfaction and retention.
- Certified Quality Auditor is highly desired.
- Certified Quality Engineer is a plus.
- Six sigma certification is preferred.
- Demonstrated ability to work cross-functionally to drive root-cause and corrective action where needed.
- Four to seven year experience leading efforts to address quality issues in Failure Review Board (FRB)/Material Review board (MRB) forum.
- In depth knowledge with performing and reviewing Process Failure Modes and Effects Analysis (PFMEA) and ability to apply its principles and results to process improvement.
- Applied experience in Statistical Process Control (SPC), Corrective and Preventive Action (CAPA), and Lean Manufacturing is highly desired.
- To be successful in this position, the candidate must have a commitment to quality in everything they do. This means continuous improvement of activities and processes. In order to do so, the candidate must show an ability to drive to root cause and resolve issues related to that cause.

Education and Experience:
- Bachelor Degree in a technical or engineering field, or 6-10 year equivalent combination of education and experience, is required.
- Experience working in an electronic Manufacturing environment is highly desired.

Physical Demands /Work Environment:
- Work cross-functionally to drive continual improvement in product and processes.
- Able to work in a noisy Manufacturing environment on an as needed basis.

Company Description:
FreeWave Technologies provides the most reliable, high-performance spread spectrum and licensed wireless data radios for critical data transmission to oil and gas, utility, military and numerous other
industries worldwide. As a market leader, we are committed to providing best-in-class radio products and unmatched customer service and support. We seek staff who are willing to help us grow and to achieve our commitments with excellence.

Our future growth requires new employees who are able to find innovative ways to contribute to the organization. We need people who are able to contribute unique skills to the team, solve problems either as a member of a team or on their own, and fully participate in achieving group results. The ideal candidate is one who is able to fit in as a member of a progressive team in a relaxed working environment. FreeWave Technologies, Inc. engineers and manufactures certain products that are considered ITAR-controlled items under the International Traffic in Arms Regulations (ITAR). Consistent with ITAR, any position at FreeWave that involves work with the engineering or manufacturing functions of the Company may only be filled by a candidate who is (i) a citizen of the United States, or (ii) a person who has been accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws.

Quality – To be successful in this position, the candidate must have a commitment to quality in everything they do. This means continuous improvement of activities and processes. In order to do so, the candidate must show an ability to drive to root cause and resolve issues related to that cause.

EOE/M/F/V/D

Corgenix Inc.

I. IDENTIFYING INFORMATION:

Job Title: Senior Quality Assurance Associate

Department: Quality and Regulatory Affairs

Reports to: Director, Quality and Regulatory Affairs

II. GENERAL PURPOSE:

Oversees Quality Assurance activities to ensure compliance with regulatory agencies, ISO, and Corgenix requirements.

III. KEY RESPONSIBILITIES:

1. Final disposition authority for incoming materials, including packaging and labeling, used in product manufacturing.

2. Manage the Approved Vendor List and vendor system, perform supplier audits.

3. Review and final approval authority for device history records.

4. Develop quality assurance policies, procedures, instructions, and records in accordance with current regulatory requirements. Present and activate such policies, as approved by management.

5. Assist in establishing document approval and change control procedures. Assist with document control procedures, as necessary.
6. Assist personnel in developing procedures, instructions, test methods, and records, as requested.

7. Assist the Director of Quality and Regulatory Affairs in scheduling, initiating, and performing departmental audits of systems and processes.

8. Final review and approval signature on validation studies.

9. Responsible for employee quality system training in accordance with regulatory requirements (QSR and ISO). This includes presenting initial QSR training for all new employees and developing annual company update training for all employees. Furthermore, this position is responsible for designing and assisting in all Quality Assurance related training.

10. Manage CAPA program to ensure timely completion of each CAPA phase and ensure the effectiveness of CAPAs.

11. Oversee coordination and maintenance of company quality training program files.

12. Final review and sign off approval for new documents/new document revisions prior to distribution.

13. Assist in FDA and ISO inspections, follow-up actions, and correspondence regarding compliance issues.

14. Assist the Director of Quality and Regulatory Affairs in the development and execution of Quality Department operational and strategic programs including work plans, short and long range goals, audit requirements, training needs, and budgets.

15. Manage filing and database inputs of quality documents (e.g. process validations, equipment validations, Action Impact Reviews, packaging and transport testing).

16. Contribute to Quality Forum newsletters, conduct training, and perform other activities to educate employees on quality concepts.

17. Final review and sign off of final product.

18. Other duties as assigned by Supervisor.

IV. CONTACTS:

INSIDE COMPANY: Works closely with Quality Control, Document Control, Manufacturing, Marketing, Regulatory Affairs, and R&D.

OUTSIDE COMPANY: Raw material suppliers concerning quality and compliance issues. FDA and ISO regarding compliance issues.

V. JOB TITLE DIRECTLY SUPERVISED: N/A

VI. WORKING CONDITIONS

This position primarily functions in a typical office environment. Due to the interaction with Quality Control, this position will occasionally function in a laboratory setting with risk of exposure to biological and chemical hazards associated with such a setting. The position requires a moderate level of mental exertion, with the individual having to respond to short deadlines and crises. The position may require in excess of forty hours per week and generate a moderate amount of stress.

VII. SPECIALIZED EQUIPMENT USED:
General office equipment including personal computer hardware, standard computer software (e.g., word processing, spreadsheet, database, statistical programs), copiers, Fax machines, paper shredder, paper binding equipment, and printers.

VIII. ACCOUNTABILITY/SCOPE OF THE POSITION:

This position is accountable for the Quality Assurance activities of the company. It is a highly visible position, integral to the company's short and long term success. This position is key to the long and short term success of the company and requires a high level of commitment to the goals set by the Quality and Regulatory Affairs Department and the company.

IX. MINIMUM POSITION REQUIREMENTS:

BACKGROUND KNOWLEDGE: A Bachelors Degree is required along with a working knowledge of Quality Assurance principles and methods.

EXPERIENCE: This position requires a minimum of 6 years working experience in a Quality Assurance role within an FDA regulated environment (Medical Device industry preferred). Knowledge of the FDA Quality System Regulation and ISO13485 is strongly preferred.

GENERAL: This person must demonstrate the ability to work and think independently and possess excellent written and oral communication skills.

Qualified candidates should send resume and cover letter to dfsimpson@corgenix.com.

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assessment and feedback, which result in continuous improvement, recognition, and awards.

Excellence conference in Littleton, CO on April 18, 2014. This event provides a rare opportunity to learn from the pro’s who have led large-scale organizational transformation. The Quest event will include national Baldrige recipients and local recipients who will share their insights on continuous improvement utilizing the Baldrige framework. Mark your calendars now and look for more details as the event grows near.

Here’s to continuing the journey toward performance excellence in 2014 and beyond!!

Respectfully,
Board Chair: Jeanne Brown
Executive Director: Kim Griffiths
Award Program Facilitator: Jim Walker

Examiner Training Dates

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