

SCOPE



The Official Newsletter of the ASQ Orange Empire Section

March 2009

Section Chair Column - ASQ Letter from the Chair



Greetings everyone,
We had good monthly dinner meeting in February with clinics on “Suppliers Risk Management” and “Interviewing skills” and out dinner meeting topic was “Increasing Customer Delight.” Due

to softening economy, we noticed that attendance was lighter than usual. I know that many members are out of a job and/or looking for a new job. During the last LC meeting, we discussed different options that would allow members to attend monthly dinner meetings. **I would like to announce that effective immediately, we will allow our out-of-work members to attend both clinic and dinner speaker’s presentation at no cost (however, no dinner provided).** To facilitate this, we have already talked to the hotel staff to set up 15 additional chairs at the back of the meeting room. As I mentioned previously, my leadership team and I are constantly for looking different ways to help our members by offering clinics that can help to enhance their knowledge. If you have other suggestions, we would love to hear from you.

Last month, I was invited to Puerto Rico to speak at the Interphex conference and exhibition. The conference gave the attendees the opportunity to receive education, training, and to visit over 350 exhibits.

Over the past couple of months, I have received positive feedback from few of our satisfied members. I would like to share feedback from Mr. Eiji Fukuda. Mr. Fukuda wrote: “I’ve noticed a significant change you made to the eSCOPE distribution. The approach is logical and makes sense to me. Saving cost and green without paper usage. It’s definitely a good KAIZEN.” Thank you Mr. Fukuda for taking time to provide feedback.

In this issue, I would like to explore on a new tripartite Technical Guidance for Development and Manufacture of Active Pharmaceutical Ingredient, being developed by International Conference on Harmonization (ICH) and it will be ICH Q11. The proposed Q11 guidance is focused on

harmonizing the technical principles relevant to the design, development, and manufacture of drug substances as part of a total control strategy designed to ensure product quality and consistency. The guidance, in general, is for APIs, including both chemical and biological entities, and is meant to further clarify guidance for those substances defined in ICH Q6A (NCE) and Q6B (Biotechnological/Biological). ICH Q11 is expected to move to Step 2 of harmonization by the end of 2009 and to Step 4 by the end of 2010.

The ICH Q11 is expected to describe in more details about the ICH M4 common technical document about the drug substance manufacturing process and process controls, material control, critical steps and intermediate control, process validation, and process development.

The ICH Q11 will envisage substantial savings in the following four major areas:

- Time spent by assessor for searching, requesting and reassessing information
- Scientific writing of initial documentation for marketing authorization application
- The cost of preparing and reviewing answers to queries for regional documentation requirements
- The cost of keeping the various regional documentation format to date

Lastly, I will be interviewing quality leaders every couple of months to publish the interviews in the eSCOPE. As a chair, my goal is to add value to our monthly publication. I would like to start with none other than Corporate VP of Quality Assurance at Edwards Lifesciences, John P. McGrath, PhD. John has supported Edwards’ employees to enhance knowledge by attending ASQ Meetings and to learn/earn ASQ certifications. I am fortunate to work for a charismatic leader who possesses great leadership skills, interpersonal skills, and inspires people working for and with him.

Please let me know if you would like to help our section by interviewing Quality Leaders at your company for publication in eSCOPE.

Bob Mehta
Chair – ASQ Section 0701
MSQA, MBA, B.S. (Chem), CQA, CQE, CSSBB, CBA, CSQE

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Please contact the Leadership Team and tell us how to serve you better

Welcome New Members



Gilbert A. Alba
Tina K. Ariaee
Pierre Bonnet
Jeffery Brian Boyd
Mai Bui
Patricia Casing
Phillip Brandon Dickson
Pilar Escano
Angelika B. Gasienica
William Georges
Kathryn Henslee
Patrick Khani
Kelly Kwo
Luis Liang

Charles J. Maronna
Vincent S. Medel
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Solmaz Moghaddam
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Du K. Nguyen
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Sunil I. Patel
Brian Pringle
P.R. Soundar Rajan
Jose A. Rodriguez
Amitoj Sandhu
Farquema Sirleaf
Vivian Tran
Julie Trieu
Zachary Wahl

Not receiving e-mail notifications of upcoming events? Call headquarters at 800-248-1946 and request the necessary changes, or e-mail them at help@asq.org

March 10 Dinner Meeting



**Doubletree Hotel,
201 E. MacArthur
Blvd, Santa Ana**

Directions: [http://
maps.google.com/](http://maps.google.com/)

Clinic # 1 is entitled:
**Comparison of ISO 9001:
2000 to 2008** presented by

Yasamin Ameri. ISO have recognized that ISO 9001:2008 introduces no new requirements. ISO 9001:2008 only introduces clarifications to the existing requirements of ISO 9001:2000 based on eight years of experience of implementing the standard world wide with about one million certificates issued in 170 countries to date. It also introduces changes intended to improve consistency with ISO 14001:2004 (Environmental Management System Requirements). As a participant in this clinic you will:

- Understand the clarifications introduced into the ! SO 9001:2008 standard
- Be able to link ISO 9001:2008 and ISO 14001:2004

Walk away with a comparison checklist

The title of clinic # 2 is “**Environmental Management is here, Is Your Organization Ready?**” presented by **Milt Krivokuca**. Regulatory reporting, going green, and clean technologies are all topics before international legislative bodies and will soon become a major issue facing every organization. For those unprepared, this new legislation will

become a giant capital pit, further draining resources during these difficult economic times. New laws will be implemented and conformance will be left to the individual companies. There is an existing environmental management system (EMS), ISO 14001, which has to-date been incorporated by organizations whose primary activities directly affect natural resources such as forests, agriculture, and lakes. In this presentation, the attendees will learn how ISO 14001 and ISO 9000 can be integrated to provide both a QMS and EMS designed to meet the developing environmental legislation.

Dr. Steve Kaye, Ph.D. will present **Your Personal Quality Program: How to Thrive During Chaos**. Many people are stunned by lost business, layoffs, and shrunken budgets. And if you stay stunned, the people who keep moving will leave you behind. This program is designed to show you an aggressive approach to survival. This program is about practical strategies and tactics for making realistic progress during chaos. In fact, the evolution of this presentation will serve as an example of what we all must be doing. This includes the management of your mind, the use of social media, and the power of creative thinking. You will gain: (1) Strategies to keep focused and productive when everything around you is going wrong. (2) Tactics for using social media tools like twitter and LinkedIn to advance your business, find a job, and manage your career. (3) A process for creative thinking that will help you solve problems, improve communication, facilitate personal growth, develop products, and have fun. Bring your brains and be prepared to think. This program could change everything.

No
photo
provided

Yasamin Ameri is a consultant with Quest International Consulting specializing in Drugs, Biologics/ Biotechnology. With over eighteen years of consulting expertise, Yasamin has been providing Quality Systems and Regulatory Affairs services for pharmaceuticals and biotech start-ups and established companies; designing and implementing QA and RA functions for start-ups and Gap analysis and internal audits for established companies. Her focus has been on quality compliance and regulatory compliance. Yasamin has served as an audit member of the ASQ Orange Empire Section Volunteer Audit team.



Milton Krivokuca is currently the coordinator for the BSQA and MSQA programs at California State University Dominguez Hills. His undergraduate degree is from the University of Pittsburgh in Management Science. He earned an MBA in Operations Management, with a focus of quality systems, from DePaul University. He also earned an MA from Purdue University in Literature. After 25 years of manufacturing related experience, he began teaching and earned a Doctor of Business Administration from California Coast University. He has numerous professional accomplishments including CQIA, CQT, CQA, CMQ/OE, CPM, CQE, CQPA, CMP certifications, and is a RAB certified ISO9000: 2000 auditor. He is currently the Quality Management Division Marketing Vice-Chair. When not teaching, he is a judge in the International Team Excellences Competition, California Team Excellence program, and an examiner for the California Awards for Performance Excellence.



Steve Kaye is an author, speaker, and certified professional facilitator who helps leaders achieve significant results. His workshops show how ethical leadership produces sustainable gains. His facilitation blends process and environment to achieve more than people thought possible. He has informed and inspired leaders nationwide since 1992, with clients that include Avery Dennison, Allergan, and AECOM. As an entrepreneur, Steve Kaye uses these tools to run his business. He has published almost 500 articles, written over 1,500 poems, and found dozens of solutions using the techniques in this presentation. With this, he is transforming his business into a significant participant in the modern workplace. He has a Ph.D. in chemical engineering from Carnegie Mellon University and 20 years of experience working for major corporations. He has written three books and appeared on radio and TV.

Press Release

**Press Contacts:**

Name: Leta Thrasher

800-248-1946 ext: 7423

American Society for Quality Orange Empire Section Earns Top Honors

Irvine, CA, February 11, 2009

The Orange Empire section 0701 of the American Society for Quality (ASQ) has earned the 2007-08 Quality Management Process Total Quality Award, one of the highest honors a section can earn in the Society. Only 94 of 255 ASQ sections earned this award for the 2007-08 year!

The Orange Empire section 0701 will be honored at ASQ's 62nd annual conference; the World Conference on Quality and Improvement, on May 16, 2008 in Minneapolis, MN. Members of the ASQ Board of Directors will present the award to the section.

The Quality Management Process (QMP) Total Quality Award is awarded to sections that have proven their commitment and ability to serving local ASQ members and the community. QMP is a management model and planning tool that assists sections in their planning and implementation of programs and services that will meet the needs of current and future ASQ members. The model is based on the plan-do-check-act cycle of continuous improvement and is proven to aid the sections in delivering superior value to their members.

In order to earn the Total Quality Award, sections must meet certain criteria. First, they must determine a section volunteer roster and set long-term targets. Second, the section must develop an annual business plan with objectives and goals. Finally, a section must meet 75% of the goals set forth in their business plan.



Congratulations to Jerry Koh!

Jerry was the winner of the drawing at last month's dinner meeting. He won a ticket for a free dinner! A winner will be announced at each dinner meeting, as an incentive to attend our monthly dinner meetings. So, don't miss your chance, sign up for the next dinner meeting. You could be the next winner!

Announcements

SATURDAY, MARCH 7TH ASQ CERTIFICATION EXAMS

The next certifications exams will be held on March 7th at two locations in Orange County:

- I. **Alcon Labs** – chief proctor Hassan Farrah
(Familiar location for section members); and
- II. **Hyatt in Irvine** – chief proctor Margaret Benavides
(Service provided to the ASQ Management Division Conference Attendees).

**Please check the exam location assigned to you! Verify that the exam location is correct (and you know how to get there)
Contact ASQ National office at www.asq.org if you have any questions or concerns regarding your exam location.**

ASQ Certification Exams are offered four times each calendar year. There are many ASQ Certifications covering various aspects of the Quality Body of Knowledge. The Orange Empire Section offers regular refresher courses to prepare qualified candidates for these comprehensive exams. Of the many nationally recognized certifications, the following eight (8) are currently included in the Orange Empire's refresher course offerings:

- 1) Inspector;
- 2) Technician;
- 3) Auditor;
- 4) Biomedical Auditor;
- 5) Manager of Organizational Excellence;
- 6) Engineer;
- 7) Six Sigma Green Belt; and
- 8) Six Sigma Black Belt.

Pre-requisites must be met before a candidate is qualified to sit for these exams. These pre-requisites include experience requirements and for the Six Sigma Black Belt Certification, one or more projects must be accepted by ASQ headquarters prior to sitting for the certification exams. All ASQ Certification Exams are offered twice each year and rotate on bi-annual schedule and require early application deadlines:

March(Spring)

June(Summer)

October (Fall)

December (Winter)

All ASQ Certification Exams are offered on this bi-annual schedule. If there is a certification, then we will offer the exam even when a refresher course is not currently offered by Orange Empire. To get a complete listing of Certifications offered and their corresponding body of knowledge, please visit www.asq.org.

It is the objective of the Orange Empire Section to provide refresher courses for those certifications and bodies of knowledge that are sought by our membership. If there is a demand for a course in our section (like Green Belt being added this year or Software), then we can offer a refresher course provided the following are met:

1. ASQ Certification is offered by ASQ and the Body of Knowledge is published;
2. Qualified Instructor (Primary) submits personal qualifications and syllabus (course outline) to Margaret Benavides, Section 0701 Education Chair;
3. The Primary Instructor (responsible for the class) conducts a workshop at a section dinner meeting on a topic within the Body of Knowledge for the certification that they will be teaching.
4. A minimum number of students is required to register by the 3rd class meeting. (Costs are commensurate with hours of instruction. Scholarships are available).
5. The Primary Instructor conducts the course and follows through on other duties such as attendance records, class surveys, etc.).

Refresher courses are provided as a service to both our membership and the Orange County Business Community. Maintaining current, complete, correct, and timely understanding of Quality Principles and Methods is paramount to business success. The current downturn in our economy has resulted in a "flight to safety" which includes QUALITY. Nothing will secure a market position more firmly than strong Quality offerings!

Finally, along with certifications and exams is a need for Proctors. Especially with the additional exam location for the March exam, we are in more need than normal. If you can volunteer Saturday morning March 7th (RE's for recertification provided), please contact the section education chair Margaret Benavides at gamargaret@gmail.com.

Mail Recertification Packages to:

Mark Belgen, 5 Tunis, Laguna Niguel, CA 92677

Course	Next Exam Prep Start Date	Exam Dates	Application Deadline
CQE	Mar 4, 2009	Jun 6, 2009	Apr 17, 2009
CQA	Mar 30, 2009	Jun 6, 2009	Apr 17, 2009

Why Become Certified? In today's world, where quality competition is a fact of life and the need for a workforce proficient in the principles and practices of quality control is a central concern of many companies, certification is a mark of excellence. It demonstrates that the certified individual has the knowledge to assure quality of products and services. Certification is an investment in your career and in the future of your employer.



SCOPE Ad Rates:

Ad Size	Inch Size	1 Issue	6 Issues	12 Issues
Full page	8.5" x 11"	\$200	\$1,100	\$2,000
1/2 Page	7.5" x 4.912"	\$110	\$605	\$1,100
1/4 Page	3.667" x 4.912"	\$70	\$385	\$700

Ad Size	Inch Size	1 Issue	6 Issues	12 Issues
Business Card (1/8 Page)	3.667" x 2.36"	\$35	\$195	\$350

Checks should be made to: ASQ Orange Empire Section, and mailed to ASQ, PO Box 14183, Irvine, CA 92614, with ad copy, instructions for placement, and frequency. SCOPE Editor: Dan Shibley 626-330-3425 or dshibley@adamscampbell.com.

Upcoming Certification Courses



Certified Quality Engineer Exam Refresher/Prep Course

Location: Alcon Laboratories, 15800 Alton Prkway, Irvine, CA

Exam Date: June 6, 2009 **Exam Application Deadline:** April 17, 2009

Course fee: \$500 plus cost of textbooks. Scholarships are available - contact Education Chair.

Time: 6:00 pm - 9:00pm. 4.2 RU's will be given for this 42 hr course.

Session/Dates: 14 sessions total: Wednesdays from Mar 4, 2009 to June 3, 2009.

Will Cover: Management & Leadership in Quality Engineering; Quality Systems Development, Implementation, and Verification; Planning, Controlling, and Assuring Product and Process Quality; Reliability and Risk Management; Problem Solving and Quality Improvement; Quantitative Methods; and exam tips.

Reference Books: CQE Primer + Solution Text, Quality Council of Indiana (required). Cost \$105.

Purchase the text directly through the Quality Council of Indiana at 1-800-660-4215 or www.qualitycouncil.com prior to the first class

The Certified Quality Engineer Handbook (recommended),

Gryna, Quality Planning and Analysis, Latest edition (recommended).

TI 36X Statistical Calculator (required).

Instructors: Linda Howe Garriz (Linda.Garriz@Alconlabs.com). Mark Lindsey (Mark.Lindsey@disney.com), cell: 714-273-2678

Enrollment: Open through April 17, 2009. Class fee must be paid by the 3rd session. No refunds after the 3rd session.

To Register For the Class: go on-line at www.asqorangeempire.org/calendar/calendar.htm. Class fees must be paid no later than 3rd session.

To Register For the Exam: go on-line at <http://www.asq.org>

Certified Quality Auditor Exam Refresher/Prep Course

Location: Alcon Laboratories, 15800 Alton Prkway, Irvine, CA

Exam Date: June 6, 2009 **Exam Application Deadline:** April 17, 2009

Course fee: \$400 plus cost of textbooks. Scholarships are available - contact Education Chair.

Time: 6:00 pm - 9:00pm.

Session/Dates: 9 sessions total: Mondays from Mar 30, 2009 to June 1, 2009. No class Memorial Day.

Will Cover: Certification overview, Auditing fundamentals, Auditor competencies, Audit preparation, Audit performance, Audit preparation, Audit reporting, Audit follow-up & closure, Audit business applications, Quality tools & techniques, plus tips & strategies on exam taking.

Reference Books: CQE Primer + Solution Text, Quality Council of Indiana (required). Cost \$105. Purchase the text directly through the Quality Council of Indiana at 1-800-660-4215 or www.qualitycouncil.com prior to the first class, or

The ASQ auditing Handbook 3rd edition from ASQ Quality Press, item # H1263, cost \$63, from qualitypress@asq.org or call 800-248-1946

Optional Texts: Quality Audits for Improved Performance by Dennis R. Arter.

How to Plan an Audit by ASQ Quality Audit Technical Committee.

Optional texts can be ordered from ASQ Quality Press Ph: 800-248-1946

Instructors: Aaron Reddoch (aaronreddoch@yahoo.com). Mark Lindsey (Mark.Lindsey@disney.com), cell: 714-273-2678

Enrollment: Open through April 20, 2009. Class fee must be paid by the 3rd session. No refunds after the 3rd session. Minimum class size: 8 students.

Quality in the Trenches



Letter from the Editor:

In this month's *Quality in the Trenches* we will be looking at how we interpret preparation for defects and potential failures with the best intentions. Starting with a little humor from IBM. We

can see that even though we may have clearly defined the purpose in our own mind, the end result can be quite different!

Dan Shibley
E- Scope editor.

They're still laughing about this at IBM:

Apparently the computer giant decided to have some parts manufactured in another country as a trial project. In the specifications, they set out that they would accept three (3) defective parts per 10,000. When the delivery came in there was an accompanying letter:

" We had a hard time understanding North American business practices. But the three defective parts per 10,000 have been separately manufactured and have been included in the consignment. Hope this pleases you."

IBM's Quality control director had laid out the specifics. Three defects per 10,000 pcs would fulfill the obligation of the contract. IBM had had several meetings on the subject, went over profit and loss calculations for this new trial project. Certainly this would work!

The project details defined and the project was authorized. However, the receiving end would not take the new project lightly, nor were they contacted to share input! They were primed with higher expectations and moved quickly to solve the dilemma!

Unfortunately for IBM and fortunately for us (as we all had a little laugh on this) that too many projects or trial runs, do not take into consideration the goals and ideals of the person receiving the project.

Both parties becoming involved at the onset highlighted some of the greatest joint projects in which I have been included.

Shared information and shared cost saving ideas (material alternatives, assembly concerns etc.) benefited all. Some of the greatest failures have been when one of the parties becomes an engineering black hole and discloses little or no information. By then, the project is so far off budget or time frame that often a point of no return is met. At times, the parties parted permanently due to the seriousness of the problem (not to mention the lost cost and potential revenue).

In today's world it is imperative that new projects get as much input up front as possible!

Look for cost savings that will help from the start, not process improved ideas that will help in the foreseeable future. We have all so much experience to share, that now is the time to use it to make an impact on new jobs and ideas that will surely bloom from this recession.

People in tough times play not to lose; conservatism rules the day. However, I would like to encourage each of us to play to win. Look for ways to be in the original mix of new projects. Volunteer new ideas often and look for ways to inject combined thoughts of supplier and customer.

Today is the day to strike with experience and ingenuity. So, if you are willing to accept three defects per 10,000, try not to build the failure into it. You may be pleasantly surprised with the ability for all to succeed at the highest level by anticipating the changing cycle of recession we are in today.

Together with expectations and experience so very high, we can make a difference; we can win the war in the trenches!

Daniel Shibley, Quality Manager; the Adams Campbell Company

Daniel Shibley has been in the Quality field since 1976 and currently is the Quality Systems Manager at the Adams Campbell Company and has been the editor of the Orange County Scope since 2001. Questions and comments regarding this article may be e-mailed to: dshibley@adamscampbell.com

Risk Assessments to Determine Audit Frequency

by Pritesh Patel

1 EXECUTIVE SUMMARY

The integration of risk management and assessments is an area that the regulatory agencies will be scrutinizing more and more in the near future. Companies should be proactively working to integrate risk management and the risk based approaches as outlined in ICH Q9 into every aspect of their processes, both operational and business. This white paper discusses the utilization of a risk tool to allow the company’s audit function to schedule audits. As a company grows and increases its strategic partners, it becomes critical that a risk tool can be leveraged when determining which of these partners should be audited in the upcoming year. Resource restraints make it impossible to audit every partner every year, yet pressure from regulatory agencies continues to demand that we are vigilant with these partners.

2 DISCUSSION

The overall strategy for implementing the risk tools was harmonized across all types of audits. The only changes that had to be made were the specific criteria used when identifying the partner’s risk profile.

Currently risk tools for raw material suppliers and 3rd party contractors have been developed. It is hoped that the company’s audit function will identify criteria for the other audit types.

The strategy used for the risk tool was to judge each partner within an audit type based upon 4 criteria. The criteria focus on the following:

- Severity to the company based on audit history
- Severity to Supply
- Probability of failures to occur
- Detectability of failures based on time since last audit / inspection.

Each criterion has four levels, and each level is assigned a point value of either 1, 3, 5, 10; where 1 is low and 10 is high.

Severity to the company based on audit history.

This criterion looks at how well our partner has done during past company audits or regulatory inspections. This criteria should be applied to all types of audits equally, that is to say, there is little change in the wording of this criteria. **Table 1** shows the scoring and description of the different levels within this criterion.

Table 1. Level description and scoring for Audit History criteria.

If...	...then ranking is...
Results from last audit or inspection was considered to be "satisfactory" OR Observations from last inspection / audit were adequately addressed	1
Results from last inspection / audit indicated minor deficiencies	3
Results from last inspection / audit indicated one or more major deficiencies	5
Results from last inspection / audit indicated one or more critical deficiencies OR No compliance history is available OR A product recall has occurred that can be linked to this vendor	10

As noted above, if the compliance history is not known, then a score of 10 is assigned to ensure that we take appropriate action.

Severity to Supply

This criterion look at what product is impacted by the partner. The product is further stratified into levels according to the revenue generated. **Table 2** shows the severity to supply when performing the risk assessment to raw materials, and **Table 3** shows the severity to supply when performing the risk assessment to 3rd party contractors.

Table 2. Level description and scoring for Severity to Supply for Raw Material suppliers.

If...	...then ranking is...
RM / Component / packaging impact one or more bottom 40% of the company's products by revenue	1
RM / Component / packaging impact one or more middle 40% of the company's products by revenue	3
RM / Component / packaging provided impact one top 20% of the company's products by revenue	5
RM / Component / packaging provided impact several top 20% of the company's products by revenue	10

Table 3. Level description and scoring for Severity to Supply for 3rd party contractors.

If...	...then ranking is...
Services impact one or more bottom 40% of the company's products by revenue	1
Services impact one or more middle 40% of the company's products by revenue	3
Services provided impact one top 20% of the company's products by revenue	5
Services provided impact several top 20% of the company's products by revenue	10

An alternative approach to this criterion is to look at the products by volume sold as opposed to revenue generated.

Probability of failures to occur

The probability of a failure to occur is based upon the complexity of the operations of the partner. It follows that a highly complex process has a higher opportunity of failures to occur, where as a simple process such as storage or transportation has a lower opportunity of failures to occur.

Table 4 shows the probability of failure when performing the

risk assessment to raw materials, and **Table 5** shows the severity to supply when performing the risk assessment to 3rd party contractors.

Table 4. Level description and scoring for Probability of Failure for a Raw Material suppliers.

If...	...then ranking is...
RM / Component / packaging is a commodity that can be purchased in the open market	1
RM / component / packaging are manufactured in a dedicated system by a supplier solely for the company's use.	3
RM / component / packaging are manufactured in a shared system by a supplier solely for the company's use.	5
RM / component / packaging are manufactured by the supplier who is a sole source supplier	10

Table 5. Level description and scoring for Probability of Failure for a 3rd Party Contractor.

If...	...then ranking is...
Vendor is a warehousing / storage / transportation service provider	1
Vendor provides non sterile filling / packaging services OR The vendor solely manufactures The company products	3
Vendor provides testing of API, Excipient, or product / device OR The company's products are manufactured in a dedicated system within a facility that can serve many of the vendor's customers	5

Detectability of failures based on time since last audit / inspection

This last criterion looks at the time since the last audit / inspection was conducted. The premise being that maximum time that can elapse before the partner gets audited or inspected is 36 months. Just like the first criterion, this criterion should be applied equally amongst the different types of audits. **Table 6** looks at the scoring and level description.

Table 6. Level description and scoring for detectability based on time since last audit.

If...	...then ranking is...
An Audit or inspection was conducted within the last 12 months	1
An Audit or inspection was conducted within the last 12 to 24 months	3
An Audit or inspection was conducted within the last 24 to 36 months	5
An Audit or inspection was conducted within the last 36 months	10

Calculating Risk Score and determining risk threshold

Once all four criteria have been applied to a partner, the risk score is obtained by calculating the product of the four criteria scores. It is recommended that any partner who has a risk score of 225 or greater be considered for an audit.

The threshold of 225 is established by considering the following...

- The partner has an audit history score of 3 or higher
- The severity to supply is 5 or higher
- The probability of a failure to occur is 3 or higher
- The detectability of failure is 5 or higher.

Calculating the product of these yields $3*5*3*5 = 225$.

Caveat

As with all risk and decision making tools, there are caveats; this one is no different. Remember that this is only a guide. If a partner has been audited last year, there should be consideration to re-audit to ensure that all CAPAs requested have been completed as committed to. For cause audits should be accommodated within the schedule, as well as any other special audits that are requested.

Conclusion

A simple yet efficient approach to using risk to determine audit schedules has been presented. As the company harmonizes its philosophy and approach to risk management, this risk tool needs to be modified to fit accordingly. Additional risk assessment tools need to be created for the other types of audits. It should be noted that the risk tools outlined in this paper should only be used as initial guides. Past audit reports need to be reviewed to fully understand if the partner needs to be audited in the upcoming year.

An Interview with Quality Leader – John P. McGrath, Corporate Vice President, Quality, Edwards Lifesciences

by Bob Mehta – Chairman ASQ Orange Empire Section 0701

John P. McGrath PhD joined Edwards in 2006 as Vice President of Quality with more than twenty years of medical device and combination product experience in quality, manufacturing and product development. McGrath was previously Vice President of Quality at Cordis Corporation, where his quality assurance responsibilities included cardiovascular, endovascular and neurovascular businesses. Mr. McGrath (JM) was interviewed by Bob Mehta (BM) by asking him the following questions:

BM: In your opinion, how has the quality role or quality field transformed over the past decade?

JM: Over the past decade, the quality role has transformed from a traditional perspective based on science and engineering to one that also considers environmental factors like the political/regulatory environment and the company's risk tolerance. In August 2002, FDA announced "Pharmaceutical cGMPs for the 21st Century – A Risk Based Approach" to encourage implementation of risk-based approaches that focus both industry and regulatory attention on critical areas to protect patient safety

BM: What are the future challenges/opportunities for quality professionals?

JM: A major opportunity for quality professionals is to continue to add value in an evolving technical, economic and social

landscape. Quality professionals can help to improve the organizational change process, lead the identification of root causes, optimize processes through work flow analysis and waste elimination, optimize specific operations through the design of experiments and monitor process performance using SPC to identify changes and trends before they become concerning. All of these tools improve cost, quality or service and add value to the business.

BM: What essential skills do the quality professionals need?

JM: The quality professional should have a basic understanding of science and engineering and a strong, pragmatic problem solving talent. We help the organization to make balanced, data-based decisions. Quality professionals must possess the knowledge, expertise and skills to create and implement efficient and effective quality systems, as well as understand the regulatory and compliance environment. Quality professionals need a working knowledge of manufacturing, product development, design control, improvement tools and relevant regulatory requirements.

BM: What would you recommend to quality professionals for enhancing their knowledge of tools and techniques used in the 21st century?

- continued on next page

An Interview with Quality Leader – John P. McGrath (continued)

JM: The quality professionals should understand the theory behind the techniques we apply to investigating and improving problems. ASQ provides many relevant courses and certifications. However, theory in itself is of limited use unless it is applied. The most valuable quality professionals are those that can utilize the theory and produce results that help the business be more successful.

BM: In your opinion, what role has ASQ played in promoting quality by offering education and career development for quality professionals?

JM: ASQ has played a very important role in providing core skills to quality professionals by offering 15 different certifications. In recent years many universities have begun to provide classes for quality professionals. However, there was a time before these existed when ASQ led the way and was an invaluable source of education – and it continues in this role today. In addition, ASQ local chapters hold monthly dinner meetings to provide education in quality methods as well as career development, quality resources and personal growth through professional and social interaction. I know you have made great contributions as a chair of the Orange Empire Section and you and your team is doing a great job with the local chapter.

BM: What areas outside of the traditional manufacturing environment do you think could benefit most from the adoption of quality principles?

JM: Quality principles can be applied anywhere there is a process and to develop

a process where one does not exist. Services can be improved using VOC to better understand customer requirements and process improvement tools to provide better, more consistent products.

BM: What do you think the next major breakthrough in quality will be?

JM: I think we will continue to see greater application and adoption of what some of us consider as core quality tools. Six Sigma revitalized design of experimentation and other basic statistical tools. I expect we will see these and other quality tools used more outside of the traditional manufacturing plant and product development team in service and other business processes, for example budgeting, recruiting, etc.

BM: What is the outlook for "Quality" professionals in coming years?

JM: The quality professionals will continue to play important roles in the coming years by helping to eliminate waste, optimize processes and better manage risks.

BM: What advice would you give to individuals just starting out with a quality career?

JM: Get early experience in manufacturing quality and product development quality. Seek out a mentor and develop a career plan with a five-year horizon.

BM: John, I appreciate you taking the time for this interview, and for sharing your views with our ASQ section 0701 members.


Meet the Leadership Team

Meet the Leadership Team will be a regular feature article for the year 2009. This month, we honor Margaret Benavides, a long-time contributor to the Leadership Committee, who always wears a smile.



Margaret Benavides currently serves as the **Education Chair** for the ASQ Orange Empire Section. She has been active on the ASQ Section 0701 Board of Directors since 2001. Margaret graduated with engineering honors (Tau Beta Pi) from San Jose State University with a BS in Materials Science Engineering and holds ASQ certifications in Quality Engineering, Six Sigma Black Belt, and Audit. She has received numerous awards for her contributions in industry and the community including ASQ. Currently working in the medical device industry, Margaret has a diverse background in electronic and tissue products and specializes in validation of process and product upgrades as well as root cause identification and mitigation. Margaret Benavides can be reached at qamargaret@gmail.com or by calling 714-654-2479

SPECIAL ANNOUNCEMENT

<p>Sun Feb 08 04:54:04 PST 2009</p>	
<p>Thank You Orange Empire Section</p> <p>~~~~~</p> <p>Thank You Orange Empire Section Bob, all of the Leadership Committee, and members of Section 701:</p> <p>I would like to say thank you for ASQ Award presented to me on January 13, 2009. I am humbled and will treasure it in honor of all those dedicated Program and Leadership Committee members who have supported me and the program for all of these years. Together, we jump, soar, and keep raising the bar; keeping Section 701 among the very best in the nation.</p> <p>Thank you for the gift certificate also. My wife, Pat, and I will enjoy it soon.</p> <p>Respectfully, Dave Nagy</p>	<p>From: Dave Nagy daven@boleroassociates.com IP: 70.187.145.132 Pickup code: m184044-mehta</p>

Thank you Dave!

During January's dinner meeting, we honored Dave Nagy for his long and dedicated service to ASQ. He was so honored and humbled by the honors that he received, and wanted to say felt compelled to say thanks to all of you for your expression of gratitude and appreciation..

Career Opportunities

Manager Regulatory Affairs Ventura County, CA

Responsibilities:

Ensure compliance with FDA and other applicable regulations and Develop regulatory strategies to facilitate submissions.
Prepare, analyze and submit reports to governing agencies to comply with regulatory requirements including ISO, local, state and/or federal requirements.
Review regulatory publications, documents and websites to stay informed about proposed regulatory changes from the FDA & other worldwide regulatory authorities to develop strategies to adjust to required changes and report on the impact of these changes.
Maintain external references along with lists of national and international regulations, standards and FDA guidance documents that affect products and operations.
Communicate with regulatory agencies on administrative and submissions.
Participate in training and education seminars to learn regulatory requirements and demonstrate RA knowledge.
Document, consolidate and maintain communications with FDA, notified bodies and registrars.
Assist with filing annual notifications, annual establishment (state and federal registrations) and product changes of FDA, Health Canada, EU, notified bodies, etc.
Compile and submit device experience reports as per FDA Medical Device Reporting System, EU Device Vigilance System, etc.
Support the design control process and provide regulatory review for design control.
Ensure consistent application of law, regulation and guidance across design projects.
Participate in and conduct internal audits, coordinates customer on-site audits and confer with representatives of material and component vendors regarding supply quality, capacity of vendor to meet orders, and vendor quality standards.
Interact with responsible departments to manage collection, reviewing and assembly of scientific, clinical, manufacturing and administrative sections of submissions.

Participate in third party audits of the quality management system and develop responses to support audit corrections and rebuttals.
Participate in product recovery process and generate regulatory risk assessments for product issues with customer exposure.
Assist with development/maintenance of regulatory files, records and reporting systems.
Review change control documents to ensure regulatory compliance.
Communicate and interface with international sales managers and international distributors to assist in international regulatory issues.
Formulate and establish company policies, operating procedures, and work instructions.
Responsible for the coordination of quality system training program for all company Medical Division personnel.
This position has direct responsibility for Logistics Quality Control Inspectors.

Experience/Education:

Bachelors Degree from four-year college or university.
3 years in a medical device regulatory environment with demonstrated supervisory/managerial progression.
5 to 7 years related experience/training; or equivalent combination of education and experience.
Knowledge of current CFR 21 Part 820, 801, 803, 814, 806, 807, 821, 822, GMP, QSR, ISO 14971, ISO 13485:2003 and EU 93/42/EEC.
Training/experience in internal auditing.
ASQ/RAPS certification preferred.

Senior Regulatory Affairs Specialist San Fernando Valley, CA

Prepare submissions to obtain and maintain approvals for conducting clinical investigations and for commercially distributing products worldwide.

Responsibilities:

Generate submissions (i.e. PMA, 510(k), PMA supplements, CE marking applications, product registrations, etc.) to obtain various worldwide approvals to

commercially distribute products.
Produce subsequent submissions (annual reports, change notifications, etc.) to facilitate the maintenance of these approvals.
Also prepare applications (i.e. IDE) for conducting clinical investigations in U.S., Canada and EU countries. Generate required submissions (progress reports, etc.) to support the continuation of clinical studies.
Submit reports and information required by the post-market vigilance systems.
Provide input to engineering teams to assure that worldwide regulatory requirements and standards are incorporated in the product development process and design/manufacture of the products.
Participate in the engineering change order process, by reviewing engineering and manufacturing document release and changes.
Review and provide input to labeling and marketing programs in reference to regulatory requirements.
Keep abreast of new or developments in various regulations and advise Regulatory Affairs management as necessary.
Interface with regulatory agency representatives as needed to accomplish the above tasks.
Other duties as assigned.

Experience/ Requirements:

B.S. in scientific discipline or engineering.
3 - 5 years experience in Worldwide Regulatory Affairs medical device experience.
Experience writing RA submissions.
Class II and Class III medical device R & D and manufacturing experience is a plus.
RAC certification is a plus.

For inquiries of these positions, please contact: Cheryl Jones
Med Exec International Phone: 818-552-2036 or 800-507-5277 ext 412
Email: recruiter@medexecintl.com Web: <http://www.medexecintl.com>

Career Opportunities

Regulatory Compliance Specialist

Ventura County, CA

Summary

Organize and manage Quality/Regulatory Compliance Documents

Responsibilities:

Establish and maintain files for each type of regulatory required documents. Facilitates timely approval and documentation of changes to documents.

Compiles and maintains control records and related files to release drawings, engineering and quality system documents.

Establish files for each piece of maintainable equipment.

Examines documents (SOPs), work instructions, drawings, change orders, and specifications to ensure compliance with regulatory and internal procedure requirements, verify completeness and accuracy of data.

Consults with document originators to resolve discrepancies and compiles required changes to documents.

Posts changes to computerized or manual control records, releases documents, and notifies affected departments.

Will be occasionally exposed to moving mechanical parts, fumes or airborne particles

Other duties may be assigned.

Education/Experience

2-3 years in a medical device regulatory environment with a Bachelors Degree OR

5 years related experience and/or training.

Knowledge of current CFR 21 Part 820, ISO 13485:2003 and EU 93/42/EEC.

Please contact:

Lewie Casey

Med Exec International

Phone: 818-552-4173

Email: lc Casey@medexecintl.com

Web: [http://](http://www.medexecintl.com)

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Contract GLP/GCP Auditor

Six-month auditing contract available for the West Los Angeles and San Fernando Valley areas. Position will be on-site 40 hours/week.

Requirements: In-depth knowledge of FDA regulations. GLP and GCP auditing experience. Experience with Biomarkers. Knowledge of HIV and Oncology therapeutic areas is a plus BA/BS in scientific discipline

Director of Regulatory Affairs

San Fernando Valley, CA

Description:

Direct the regulatory affairs specialists in the preparation of submissions to obtain and maintain approvals for conducting clinical investigations and for commercially distributing products worldwide.

Responsibilities:

Generate or direct regulatory affairs specialists in the preparation of submissions (i.e. PMA, 510(k), PMA supplements, CE marking applications, product registrations, etc.) to obtain various worldwide approvals to commercially distribute products.

Oversee the subsequent submissions (annual reports, change notifications, etc.) to facilitate the maintenance of these approvals.

In conjunction with Clinical Research, prepare or direct regulatory affairs specialists in the generation of applications (i.e. IDE) for conducting clinical investigations in U.S., Canada and EU countries.

Ensure that all reports and information required by the complaint reporting and postmarket vigilance systems are submitted.

Provide input to engineering teams to assure that worldwide regulatory requirements and standards are incorporated in the product development process and design/manufacture of the products.

Participate or direct the staff in the engineering change order process, by reviewing engineering and

manufacturing document release and changes.

Review and provide input to labeling and marketing programs in reference to regulatory requirements.

Keep abreast of new or developments in various regulations and advise senior management as necessary.

Interface with regulatory agency representatives as needed to accomplish the above tasks.

Experience/ Requirements:

B.S. in scientific discipline or engineering.

10 – 15 years of experience in the area of worldwide regulatory affairs (both submissions and compliance) at medical device companies, preferably under the Class III/active implantable device manufacturing environment. Must have supervisory experience of professionals.

Good working knowledge of U.S. FDA, Canada and EU regulations & standards.

RAC certification is a plus.

Please contact:

Cheryl Jones

Med Exec International

Phone: 818-552-3673

Email: cjones@medexecintl.com

Web: <http://www.medexecintl.com>



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Dave Nagy, Principal



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