Customer-Supplier Division
The Global Voice of Quality™

The Partnership news

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The Partnership News is the official publication of the Customer-Supplier Division of ASQ.

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From the Chair

I wish you a happy spring.

While the calendar says it is spring, in the world of supply chain management it is hardly spring.

The three-headed disaster in Japan and political unrest in the Middle East and North Africa are having significant impacts on supply chains everywhere. Seems like every day I read an article related to risks in the supply chain.

Companies are rethinking chasing cheap labor with the threat of ever rising transportation costs. Companies are rethinking just-in-time practices especially when purchasing materials and components from single source suppliers. Suppliers that have huge market share in a specific component or material are considering geographically dispersing production.

It is a tumultuous time in our profession. And in these turbulent times it is important for our CSD community to share lessons and advance new practices that create even more effective supply chain management. We can best learn together. I encourage you to engage with peers in any way you can.

The CSD provides many opportunities to learn and exchange ideas with peers. Attend or deliver a road show or a webinar. If you come to the World Conference on Quality and Improvement, stop by our booth and attend some of the four sessions hosted by our community. Write an article for this newsletter and share your experiences so we can all improve. And of course join the CSD leadership team.

If you have other ideas on how to advance our profession, let me know.

Warmest regards,

John Blakeley

From the Editor

As I write this, I am counting the days to the World Conference on Quality and Improvement. I've finished one of my slide sets—the "big" one, and still have some work left to do on the others. I'm looking forward to networking at the conference, seeing old friends, and making new ones. I'm also at work transitioning the newsletter editor role to Hitesh Sutaria. I've enjoyed being your editor over the past few years, reaching out and connecting with new people, and developing a list of folks who I know I can count on to provide content for the newsletter. I know that I'm leaving the newsletter in confident hands. And I've enjoyed hearing from members who were excited about the things they were reading in the newsletter. It has been an honor to serve you in this capacity, and I look forward to serving in other capacities in the future.

Yours in quality,

Aimee H Siegler

Provenance in the Supply Chain: Transparency and Accountability Under the FCPA and Bribery Act

by Thomas R. Fox

Editor's Note: *This article was originally published in the FCPA Compliance and Ethics Blog on October 20, 2010.*

In the October 2010 issue of the Harvard Business Review there is a Spotlight article on *"The Transparent Supply Chain".* In this article, author Stephen New discusses the evolution in Supply Chain from opaqueness to transparency and focuses on the "quality, safety, ethics and environmental impact" of the Supply Chain on the triumvirate of companies, customers and government. New terms this information as *"Provenance"* and this is relevant both up and down the Supply Chain.

New points out that customers are becoming increasingly concerned with not only the authenticity of the goods they purchased but also the ethics of how the goods were manufactured in the Supply Chain. Companies have long been concerned with the quality of goods and services they receive from their Supply Chain vendors and tracking this information can provide assurances of high quality control. Increasingly the third prong of the triumvirate, the government, is now requesting such information and such transparency in the area of anti-corruption and anti-bribery compliance.

Under both the US Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, it is now critical that companies bring their Supply Chain vendors into their overall compliance programs. This message has been given renewed emphasis with the recent report in the FCPA Blog (and others) that the freight forwarder Panalpina may be close to a settlement with the Department of Justice (DOJ) over its FCPA violations. One of the major fallouts from the Panalpina case was the ripple effect through the energy industry, after the initial disclosure that Panalpina had paid bribes in Nigeria, while working as a freight forwarder to Vetco Grey. Other energy companies which had used Panalpina to bring goods and materials into Nigeria came under DOJ investigation for possible FCPA violations; these other companies were reported to include Transocean, GlobalSantaFe Corp., Noble Corp., Tidewater, Nabors Industries, Tidewater, Schlumberger, Shell and Global Industries.

In addition to the effect of the Panalpina matter, the new released UK Bribery Act Consultation Guidance specifically lists due diligence on Supply Chain vendors as a key component of its anti-bribery and anti-corruption best practices. Principle Six of the Guidance states, *"The commercial organisation has due diligence polices and procedures which cover all parties to a business relationship, including the organisation's* ***supply chain,*** *agents and intermediaries, all forms of joint venture and similar relationships and all markets in which the commercial organisation does business."* This means that due diligence should be engaged to establish whether individuals or other organizations involved in key decisions have a reputation for bribery and whether anyone associated with them is being investigated, prosecuted, or has been convicted or debarred for bribery or related offences. Consideration should be given to the risks associated with politically exposed persons where the proposed business relationship involves, or is linked to, a prominent public office holder. Lastly, a review of Supply Chain vendors own compliance programs should be effected.

All of this brings us back to New's article and his terminology of *"Provenance".* In the FCPA/UK Bribery Act context this should be defined as full transparency and accountability in all areas of due diligence and the relationship after the contract is signed with the supplier. A company should, on a periodic basis of not less than every three years, conduct rigorous compliance audits of its operations with its Supply Chain vendors. These audits would include, but not be limited to, detailed audits of the Supply Chain vendor's books and records, with specific attention to payments and commissions to agents, consultants, contractors, and subcontractors with responsibilities that include interactions with foreign officials. This compliance audit should include interviews with employees, consultants, agents, contractors, subcontractors and joint venture partners. Lastly a review of the FCPA compliance training provided to the Supply Chain vendor should be included.

Just as *Provenance* is the new by-word in Supply Chain management in the Harvard Business Review; transparency and accountability in the area of anti-corruption and anti-bribery should have the same urgency to companies' subject to the FCPA and/or UK Bribery Act. The Panalpina case is a stark reminder of the need for continued diligence, before and after the contract is signed, in the compliance arena.

The author can be reached at tfox@tfoxlaw.com.

Supplier Audit Evidence

by John G. Suedbeck

For those of us in the pharmaceutical industry with a U.S. market, desktop audits of suppliers is still allowed, at least for now. However, we should be assessing risk in accordance with ICH Q9 guidance.

While assessing risk using data obtained from a desktop audit, I felt the need to clarify the reliability of the evidence obtained. I reviewed my quality auditing texts, notes, and articles but found little that helped. The most relevant information came from financial auditing best practices[1]. I believe, with a little tweaking, this information will be helpful for quality auditors assessing supplier risk as well.

First, let me submit six broad categories of evidence from which the auditor can choose:

1. Confirmations. I read the SOP, now I can obtain confirmation by interviewing operators.
2. Documentation. This one is clear.
3. Analytical evidence. Consider this as your company's quality history review for the item or service purchased. This category of evidence may also include an understanding of the supplier's business and industry.
4. Inquiries of the supplier. Obtaining written or oral information from the supplier. This would include the self audit.
5. Re-performance. This would be your company's testing of the item to ensure it meets your quality requirements.
6. Observations. This one would include being on-site and verifying the supplier has the technical ability to make the item. This helps in trying to establish the actual manufacturing site. This one also includes observing operators performing a task and confirming they know what to do and they have all that they need to do what they have been asked to do (training, tools, time, etc.)—and that they can perform the tasks successfully.

Review your evidence for reliability based on the relevance of the evidence to the premise, and given relevance, the sufficiency and competence of the evidence collected based on the guidelines below.

1. Objectivity
   Objective evidence versus subjective evidence. Objective evidence is achieved when two or more auditors working independently are very likely to arrive at the same result.
2. Documentation
   Documented evidence, such as records, provide evidence for compliance to procedures. Documented evidence is more reliable than verbal.
3. Externality
   Third-party evidence may be more reliable than evidence from within the organization being audited.
4. Sample Size
   Larger samples may be more reliable than smaller samples.
5. Sampling Method
   Was the sample method appropriate?
6. Corroboration
   Corroborated evidence is the same or similar to evidence from two or more independent sources and may be more reliable than uncorroborated evidence.
7. Timeliness
   Timely evidence is typically more reliable than evidence produced after a delay.
8. Authoritativeness
   Evidence obtained from the machine operator may be more reliable with regard to how well a particular machine works than evidence from the engineer who built the machine.
9. Directness
   Interviewing and observing the operator perform the task may be more reliable than reviewing the work order steps. Also, an original document is more reliable than its copy.
10. Adequacy of Controls
    Evidence from a system or process adequately controlled is more reliable than evidence from a poorly controlled or questionable system or process.

I submit that there is a need to review the reliability of quality auditing data (obtained from an on-site audit, desktop audit, or third-party audit) before it is used to assess overall risk. Financial auditing best practices provide, with a little tweaking as described above, a useful method quality auditors can use in performing this task. While this approach was developed to comply with pharmaceutical industry requirements, it can be applied in other industries as well.

Reference

1. Internal Auditor, August, 1998 by Richard L. Ratliff, I.

About the Author

John G. Suedbeck is a quality specialist for Metrics Inc. He holds an associate degree in environmental engineering technology and a bachelor's degree in analytical chemistry. He has more than 20 years of pharmaceutical experience in development, manufacturing, and quality assurance and is an ASQ CQA, CMQ/OE, and CQIA.

World Conference on Quality and Improvement Update

Join the Customer-Supplier Division at the World Conference on Quality and Improvement in Pittsburgh, PA! The division is sponsoring four presentations this year:

- Session M17, "Solving Supply Chain Problems With TRIZ," presented by **Maria Stoletova,** Monday, May 16, 4:15 p.m.–5:15 p.m. Stoletova will introduce TRIZ and demonstrate how this structured method for innovation can be applied in the supply chain environment.
- Session T18, "Putting Service Back Into Public Service: Transformation," presented by **Stephen Hacker and Segakweng Tsiane,** Tuesday, May 17, 10:45 a.m.–11:45 a.m. This session explores how the Botswana immigration department was able to completely transform itself, turning around performance and service levels and replacing complaints with scores of testimonials.
- Session T27, "Supplier Certification Through Risk Assessment," presented by **Clayton Lessmeister,** Tuesday, May 17, 2:45 p.m.–3:45 p.m. Lessmeister will discuss the use of risk assessments to clarify specifications with suppliers and how to feed this information into supplier certification efforts.
- Session T32, "Managing Hazardous Substances in the Supply Chain," presented by **Aimee Siegler,** Tuesday, May 17, 4:00 p.m.–5:00 p.m. Siegler will discuss the impact of RoHS on companies manufacturing electrical and electronic equipment (EEE) and the need for a more active risk management focus.

Additionally, you can find CSD at our booth at the World Conference Exhibit Hall! You can find CSD in booth 235, near the ASQ Center, during exhibit hall hours Monday and Tuesday. Come by to meet division leadership, find out how you can get involved in division activities, and let us know what topics you would be interested in learning about.

We hope to see you there!

Customer-Supplier Division Earns Recognition

The Customer-Supplier Division met the requirements for the J.S. McDermond Total Quality Award for the 2009-10 year! This award, part of the quality management process (QMP) recognition program of ASQ, is a top honor. The division leadership complied with all minimum requirements, submitted an annual business plan and budget, and completed the activities on the business plan with at least 75 percent of the goals obtained.

The division will be honored at the QMP awards ceremony at the World Conference on Quality and Improvement, Saturday, May 14, 2011.

Thanks to our membership for a great year and to our member leaders for their diligence and dedication!

ASQ

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JULY 2011 ROAD SHOWS

Supplier Auditing (taught by Dennis R. Arter)
Supplier Certification (taught by Dick Gould)
Supplier Nonconformances (taught by Kathryn Roberts)
Business Continuity (taught by Betty Kildow)

Four one-day seminars
Attend one or two

Four locations in the Midwest
July 18–22, 2011

	Location	Supplier Auditing *or* Supplier Certification	Supplier Nonconformances *or* Business Continuity
Naperville, IL	**Hilton Garden Inn Naperville** 28351 Dodge Drive Warrenville, IL 60555 630-393-3223	Monday, July 18	Tuesday, July 19
Benton Harbor, MI	**Lake Michigan College** 2755 E. Napier Avenue Benton Harbor, MI 49322	Tuesday, July 19	Wednesday, July 20
Ft. Wayne, IN	**Marriott Fort Wayne** 305 E. Washington Center Road Ft. Wayne, IN 46825 260-484-0411	Wednesday, July 20	Thursday, July 21
Indianapolis, IN	**Hilton Garden Inn Indianapolis NE** 9785 North by Northeast Blvd. Fishers, IN 46037 317-577-5900	Thursday, July 21	Friday, July 22

Duration and Location

Registration starts at 8:00 a.m. with coffee and tea available. Each presentation will start at 8:30 a.m. and finish at 5:00 p.m. with 30 minutes for lunch. A certificate for 0.8 ASQ recertification units will be provided to each participant.

Seminar Fee and Registration

Cost is $400 per participant for a single seminar or $650 for two. Three or more employees from the same company may attend for $325 per participant for a single seminar or $600 for two.

Fee includes lunch, seminar notes, and a textbook.

Technical questions?

Contact: Dennis (509-783-0377), Dick (623-546-7821), Kathryn (919-870-7712), or Betty (765-483-9365).

Registration questions?

Contact ASQ Customer Care at 800-248-1946 or help@asq.org.

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