www.qualityprogress.com | June 2014

QUALITY PROGRESS | JUNE 2014

QP
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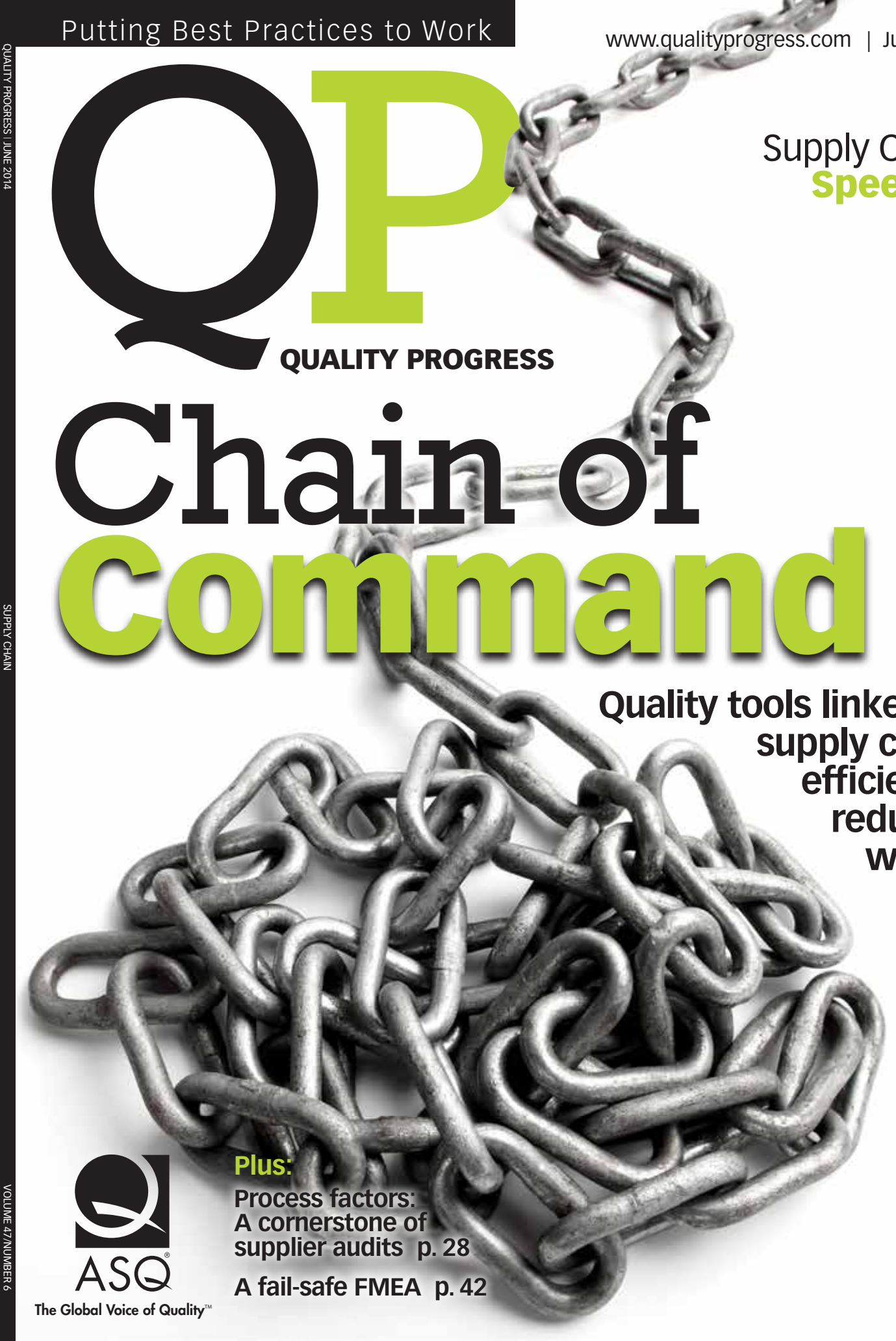
Supply Chains **Speed Up**
p. 22

Chain of Command

Quality tools linked to supply chain efficiency, reduced waste
p. 14



Plus:

Process factors: A cornerstone of supplier audits p. 28

A fail-safe FMEA p. 42

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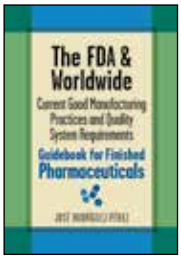
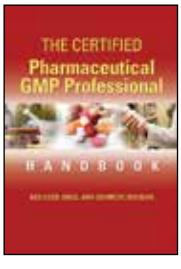


The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements for Finished Pharmaceuticals

This guidance book is meant as a resource to manufacturers of pharmaceuticals, providing up-to-date information concerning required and recommended quality system practices.

Item: H1458



The Certified Pharmaceutical GMP Professional Handbook

The purpose of this handbook is to highlight and partially annotate what the founders of the Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination believed to be the main topics comprising worldwide pharmaceutical good manufacturing practices (GMPs).

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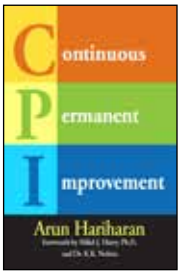

Continuous Permanent Improvement

The purpose of this book is not to expound any new theory or tools, but to share experiences in implementing existing methods with a bias toward business results. In fact, one of the important lessons we have learned is that most existing models or methods, if adhered to in the right spirit, will give results.

Item: H1466

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Contents

FEATURES

34

14

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- **Expanded Answer**
  More detail on evaluating equipment, addressed in this month's Expert Answers department (pp. 8-9).
- **Screen Time**
  View a video of William Minckler, author of "Insurance Policy," pp. 34-40, discussing more about enterprise content management systems.
- **Bonus Sidebars**
  Additional sidebars detailing more about one government agency's content management system, the subject of "Insurance Policy."
- **More to 3.4**
  An extended version of the useful tips included in "Conducting FMEAs for Results" (pp. 42-45), this month's 3.4 per Million column.
- **Added Illustration**
  An additional graphic to complement "Curve Your Enthusiasm" (p. 72), this month's Back to Basics column that covers operating characteristic curves.
- **Volviendo a los Fundamentos**
  Back to Basics translated in Spanish

DEPARTMENTS

10

COLUMNS


48

SPECIAL SECTION: 2014 SOFTWARE SHOWCASE AND DIRECTORY p. 54

NEXT

- **BENEFITS OF BLOGGING**
Writers share why it matters.

- **NEED TO NETWORK**
Tips on making valuable connections.

ASQ's Vision: By making quality a global priority, an organizational imperative and a personal ethic, the American Society for Quality becomes the community for everyone who seeks quality technology, concepts or tools to improve themselves and their world.

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Low Blow

Identifying true costs in a supply chain

LOGICALLY, IT MAKES perfect sense that the lowest-priced product doesn't always come at the lowest cost. Supply chain inefficiencies—such as wrong quantities, incorrect timing or service issues—all factor into total cost. If even one of these is off, it can throw a whole system of processes into a tailspin.

Given the complexity of global supply chains, however, sorting through and strengthening the many interrelated links can be daunting. That's where quality comes in. In this month's cover story, "No Weak Links," p. 14, the authors provide a look at a telecommunications organization that examined its supply chain's efficiency using three quality tools: value stream mapping, eight rights and seven supply chain wastes. Applying these tools helped the organization thwart suboptimization and streamline key processes.

"Need for Speed," p. 22, explores this increasingly important requirement of being quick to market and explains that flexibility is a crucial element to competitive dominance. The article includes a list of tips for prioritizing in-house product development and ultimately, beating out the competition. Decisions related to outsourcing to secure the right resources are also key, and the authors provide some criteria and food for thought on making those crucial decisions.

Speed of delivery is also the impetus behind recent innovative expansion in Amazon.com's business model. The online retailer is piloting the use of its own delivery fleet, creating a new competitive force within its established delivery network by going up against partners including FedEx and UPS. Will the model work? Could it become a new service standard? Will consumers' demand for quick delivery become a marketplace requirement? And how can quality be preserved in an on-demand world? Read "Amazon's Going the 'Last Mile'" on p. 10.

Thoughts or comments on the topics covered in this issue? Email me at ssanders@asq.org. QP

Seiche Sanders
Editor

Don't forget to watch the new episode

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Remembering a teacher

Thank you for publishing Connie Borror's excellent review of Lloyd Nelson's contributions to the quality and statistics communities in "Statistics Roundtable: A Quality Practitioner's Friend" (April 2014, pp. 46-47). I had the great privilege of knowing Lloyd over a 10-year period from 1956 to 1966 when we worked at General Electric (GE) Lighting in Cleveland. Lloyd was the consulting statistician for the lighting division of GE. I was a young engineering supervisor of quality assurance sampling inspection and testing at the 10 assembly plants of the lighting division's large lamp department. We had a great "Mutt and Jeff" relationship.[1]

In addition to teaching frequent courses on applied statistics, Lloyd found time to mentor me in applied statistics and I, in turn, coached him on the cultural and technical intricacies of the highly automated and high-speed assembly of incandescent, fluorescent and high-intensity discharge lamps.

Lloyd had a great capacity for understanding people and a strong drive to ensure that students in his courses not only learned how to turn the cranks of statistical calculations but also to understand why, where and how to use them. He urged colleagues to know how to correctly interpret results. He had a wry sense of humor that made learning from him a joy.

One of the gems I always remember is: "If one doubts the need for controls in an experiment, reflect on the following conclusion: It has been proven by aboriginal tribes over hundreds of years of experiments that the beating of tom-toms will restore the sun after an eclipse." Lloyd will be greatly missed and fondly remembered by his many students and mentees.

Bob Abbott
Louisville, KY

NOTE

1. "Mutt and Jeff" was a popular American newspaper comic strip about two mismatched characters.

Experience is key

In response to "Standards Outlook: Do You Really Understand?" (April 2014, pp. 48-49): This is a fantastic article by one of my favorite authors of all time. J.P. Russell is straightforward, humorous and right on the money. When I saw this article, it was the right thing at the right time. We are struggling with this problem in the Army acquisition business in the quality field: How do you know whether your contractor is doing what you intended in the quality sections of the contract if you don't know what the outcome should look like? So we ran internal quality classes, but we can't give the attendees the all-important missing piece—experience. Still, we must try.

Nora E. Iversen
Royal Oak, MI

Real-life odds

"Probing Probabilities" (March 2014, pp. 18-22) was one of the best articles that I have read in a long time. Recently, I was stopped at the airport security after they did the initial "check for residue on your hands" test. I failed the initial test, and so they had to do it again and the second time failed. Finally, the third time I passed. I am guessing this same theory worked for this test, too. I am sure the test is not that accurate, and the chance of it being positive is very rare. Because I had read the article, I didn't get concerned about not passing.

Doug Von Feldt
Lawrence, KS

Tune In

The ASQ TV episode available June 3 focuses on teams. In the episode:

- Learn about the International Team Excellence Award process.
- See how Coca-Cola improved customer satisfaction.
- Discover ways to enhance your team's creativity.

Watch for another episode later in June on data management. Visit **http://videos.asq.org** to access the full video library.

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- **More to the answer**
  Read an expanded response about evaluating equipment capability, one of the topics addressed in this month's Expert Answers department (pp. 8-9).
- **Extra details**
  View additional sidebars from the article "Insurance Policy" (pp. 34-40) that explain more about how a government agency designed and deployed an enterprise content management system using quality principles.
- **Screen time**
  View a video of William Minckler, author of "Insurance Policy," pp. 34-40, discussing more about enterprise content management systems.
- **Illustrated curve**
  An additional graphic adds to this month's Back to Basics column (p. 72), which covers operating characteristic curves.

QUICK POLL RESULTS

Each month at www.qualityprogress.com, visitors can take an informal survey. Here are the numbers from last month's Quick Poll:

What do you think is the most challenging aspect of working with a team?

- Engaging all members. 40.4%
- Managing various personalities. 34%
- Communicating. 25.5%
- Generating ideas. 0%

Visit www.qualityprogress.com for the latest question:

Which aspect of supply chain optimization would most benefit your organization?

- Eliminating waste within the chain.
- Identifying and partnering with the right suppliers.
- Managing processes effectively.
- Auditing suppliers accurately.

QualityNewsTODAY

Recent headlines from ASQ's global news service
(All URLs case sensitive)

7 Things Great Employers Do

Gallup has uncovered seven unusual, innovative and proven tactics to create productive and profitable working environments. As a recipe for an engaged workforce, these are ingredients Gallup says it feels confident recommending. (http://bit.ly/7greatthings)

Transforming Safety Culture Saves Organization $100M

Using the language of retail rather than risk management and applying tools not usually used in risk management to aspects of its stores' business, supermarket chain Safeway Inc. has created a culture of safety program that is saving the company millions of dollars in workers' compensation and general liability costs. (http://bit.ly/safetyculture)

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Driving service quality

Q: How do you drive quality for an IT department in the service sector, such as at a bank?

Zaheer Ahmed
Riyadh, Saudi Arabia

A: Many will say to drive quality in IT, you must focus on using methods such as the capability maturity model integrated (CMMI), lean Six Sigma or the project management body of knowledge. While many organizations struggle with which improvement method to use, their operational area's service delivery to internal and external clients is feeling the impact of poor quality.

If you are interested in driving quality within an IT department in a bank, there are three avenues to focus on:

1. The problems.
2. Moving from problem containment to true root cause.
3. Leveraging a maturity model.

First, focus on the problems, not the method. Using a hybrid, pragmatic approach to method selection is a good way to proceed. In addition, you may want to leverage metrics to help you identify where to focus.

Many IT service areas have metrics, but few of those metrics are linked to known problem areas for clients. Sometimes, IT departments don't measure what matters for their clients. In a previous career at a major bank, my department was getting feedback from the retail area that network operations were causing major downtime. Staffing issues resulted from the systems going down, and the staff members had to refer to hard-copy ledgers.

There was an effort to normalize the actual downtime data across all of the retail branches. This had not been done before and turned out to be extremely beneficial. After that metric was produced and shared, the tone of the conversation changed. When the retail bank saw how small the actual downtime per branch was, the IT department was able to become proactive and begin efforts to reduce the downtime even further. It would have been difficult to change the relationship with that client without that metric.

It's important to ensure that metrics are linked to problem areas. In the past, operational leaders would approach a continuous improvement team and say, "We need your help." That's honorable, but knowing which critical problems to focus on is important.

In that vein, if you happen to be on the receiving end of IT service (Who isn't these days?), ask yourself, "What is keeping me up at night?" or "What is my No. 1 problem?" Then, ask yourself, "Do I have metrics or goals relevant to those problems?" Chances are, the answer will be no. If the answer is no, don't be discouraged. This is a common problem and a great way to find out where to focus quality or improvement efforts.

Second, moving from problem containment to true root cause is another great place to focus. Many IT shops stop at containment and fail to move to true root cause. Containment is generally defined as the effort that stops the bleeding and restores service, but that doesn't address the root cause.

Improvement only starts when you systematically start looking for true root cause. Team-oriented problem solving is useful for this as it forces the distinction between containment and true root cause.[1]

Third, using a maturity model can be helpful for getting started on implementing quality in any area. The notion of a maturity model is that it forces users to come to grips with where they are on their journey. If you have a resource on your team with an in-depth quality background, he or she should be able to help leverage this tool.

Quality maturity models are broken down into levels, with each level being characterized by traits of your current and future states of quality. The first levels have few characteristics associated with them. As you move up, you will find that the information under each level increases. You also will notice increased granularity as you move up the levels.

As an example, metrics should be an element of the maturity model. You may find metrics at level one are ad hoc or nonexistent. Level two may have metrics as present, but purely reactive in nature. Level three may have metrics as present and used as needed. Level four may say that they are integrated into each area and supported by measurement system analysis. Level five may represent proactive use of data, generated by both internal (client needs) and external (benchmarking) perspectives.

Using these tips, pull a small team together and get started. Your efforts will quickly be noticed and appreciated.

Keith Wagoner
AVP Partner Solutions
Lincoln Financial Group
Greensboro, NC

REFERENCE

1. Keith Wagoner, "8D Solutions," *Quality Progress*, November 2009, pp. 8-9.

Evaluating equipment

Q: How do you evaluate capability of equipment such as pumps, heat exchangers and furnaces?

Rajendra Prasad Yalamanchily
Secunderabad, India

A: Capability evaluation of equipment deals with studying the process and output of the equipment with respect to its ability to fulfill

its intended purpose. This concept is related to process validation, which is defined in the U.S. Food and Drug Administration's quality system regulation as "establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications."[1] Therefore, this answer addresses the phases of process validation to ensure that equipment is designed correctly and that it has the required initial short-term and long-term capability.

Qualification is another related, more broadly used term that you may be more familiar with. The sequence presented in Figure 1 consists of design qualification (DQ), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).

When equipment arrives from a vendor or internal fabricator, DQ verifies that the equipment is what was ordered. The equipment should be inspected thoroughly for overall appearance and damage. The vendor's records that arrive with the equipment also should be inspected.

Then, the equipment can be installed and further evaluation can begin. A process validation guidance document defines IQ as "establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered."[2] The following tasks are among those typically performed at IQ:

- Determine installation requirements and connect power sources and utilities.
- Verify the machine controls and settings work as intended. This is the first hint of establishing statistical capability.
- Determine the calibration and preventive maintenance tasks and schedule, and affix appropriate tracking stickers.
- Write manufacturing procedures for the care, cleaning and use of the equipment.

The next phase is OQ. Here, the equipment is run at combinations of upper and lower operating limits, sometimes referred to as worst case conditions. If applicable, raw materials encompassing the entire range of critical characteristics also should be used in these studies.

OQ provides the opportunity to use basic and advanced statistical tools. Design of experiments is particularly helpful, including simple factorial designs that allow for a process model to be developed and interactions to be determined. The statistical demonstration of an entire experimental design space meeting the process requirements is a powerful argument for the capability of the equipment. Another advantage of the process model is that predictions can be made regarding combinations of variables that are not explicitly combined in the experiment.

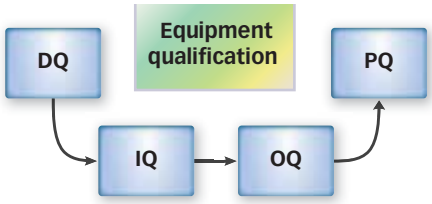
Analysis of variance (ANOVA) is another useful tool. For an oven, for example, thermocouples can be placed at strategic locations and temperature profile data collected over time at different set points. ANOVA can be used to detect hot and cold spots. In addition, statistical analysis can be performed to determine oven locations of relatively high variation. There also may be opportunities to use correlation and regression. For a pump, for example, plots of output versus set point can determine areas of concern with respect to deviation from expected values.

Lastly, PQ is executed to verify the long-term capability at standard operating conditions. The equipment is run at its nominal conditions, perhaps near the center of the combination of parameters that comprised the OQ. Data are collected for an extended time, at least long enough for all reasonable sources of variation to occur. Often, the rule of thumb is that three production lots should be run. Perhaps obtain data on product from three lots of raw material processed by three different operators during three different shifts. Enough data should be collected to determine true stability and capability in a time-series analysis.

All of these activities, taken together, should achieve the goal of process validation to demonstrate that the process, including qualified equipment, consistently produces a result or product meeting its predetermined specifications.

Scott A. Laman
Senior manager, quality engineering and risk management, Teleflex Inc.
Reading, PA

Recommended qualification sequence / FIGURE 1



DQ = design qualification
IQ = installation qualification
OQ = operational qualification
PQ = performance qualification

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2. Global Harmonization Task Force, Study Group 3, *GHTF/SG3/N99-10:2004 (Edition 2)—Quality management systems—process validation guidance*, January 2004.

EDITOR'S NOTE
A more detailed version of this response can be found on this article's webpage at www.qualityprogress.com.

SUPPLY CHAIN MANAGEMENT

Amazon's Going the 'Last Mile'

Could online retailer's delivery service change e-commerce expectations?

In 1994, Amazon.com was launched as an online bookstore operated out of the Bellevue, WA, garage of founder and CEO Jeff Bezos. It's since grown to become the largest online retailer in the world, selling everything from beauty products to lawnmowers.[1]

Technological innovation has powered much of Amazon's growth—from one-click purchases, which dramatically speed up the ordering process, to recommendations based on previous purchases and rated items. Its grocery service ships 45 pounds of nonperishable items to customers' homes at a flat shipping rate of $5.99.[2] Recently, the retail giant unveiled a new service in the form of a delivery method that could change the online shopping experience and influence consumer expectations.

After rolling out the service in the United Kingdom earlier this year, Amazon is piloting its own private fleet of delivery trucks operated by contract drivers in three U.S. markets—New York City, Los Angeles and San Francisco. Amazon also built its own parcel tracking system, similar to those used by the United Parcel Service (UPS) and FedEx.[3]

How exactly this works isn't yet clear. It focuses on the "last mile" of deliveries, however—the part that ends at your doorstep and is typically handled by large carriers such as UPS, FedEx or the U.S. Postal Service.

"One thing Amazon has done very successfully is they've owned the entire value chain," said Sucharita Mulpuru, a retail analyst at Forrester Research. "They've owned the last mile, the moment that matters. That moment is when the package arrives. Once you can own the moment that matters, you build a loyal customer base."[4]

Race for the last mile

According to the Network Effect, a blog that analyzes supply chain trends, the supply chain used to be a relative backwater for retailers. Historically, retailers only needed to keep pace with industry averages. But the status quo might not be enough in today's increasingly competitive marketplace.[5]

A recent large-scale consumer survey by Ernst and Young found that the top influencer in consumer purchasing decisions was delivery terms, trumping the power of promotional offers, physical store design and website strength. Almost a third of consumers surveyed said they were willing to pay a premium for instant or swift product availability.[6]

Greater demand for convenience helps explain the strategy that Amazon is following. Its massive expansion of building fulfillment centers (adding 50 new facilities since 2010) could position Amazon to eventually offer same-day delivery throughout the United States.[7]

In a widely publicized announcement, Amazon detailed its plan to eventually use pilotless flying drones to deliver packages to customers within a half hour of placing an order. Even if delivery by drone turns out to be a pipe dream, Amazon's recent moves could be a game changer.[8] Taking control of delivery could allow Amazon to better control consumer experiences. Over time, online shoppers may become accustomed to accelerated delivery options without a lot of extra expense.[9]

"Retail is at a crossroads," said Jim Tompkins, president of Tompkins International. "The reality is that Amazon is so big that they are now mandating what the customer satisfaction requirements are for everyone, even if you don't think that you compete with Amazon."[10]

Other retailers are using similar delivery strategies. EBay offers local delivery in less than two hours for $5 in several urban regions: Chicago, Dallas, Manhattan, Brooklyn and Queens in New York, and San Francisco. Google Shopping Express, available in San Francisco and San Jose, delivers packages the same day for $4.99 per order.[11]

Logistics

For now, Amazon will still rely on FedEx, UPS and the U.S. Postal Service to move goods elsewhere in its supply chain. Shipping costs are a major line item in Amazon's cost structure and are rising.[12] In its first quarter earnings report, Amazon's sales were up 23%, but shipping costs were up

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31%. Sanford C. Bernstein & Co. analysts estimate Amazon shipped about 608 million U.S. packages in 2013. The Postal Service handled 35%, UPS 30%, regional shippers 18% and FedEx about 17%. The distribution hasn't changed much in recent years. Amazon typically pays between about $2 and $8 to ship each package.[13]

Amazon began planning the delivery network several years ago. Shipping issues experienced by UPS and FedEx last holiday season added urgency to rollout of the service.[14]

Amazon shipments should account for less than 1% of revenue for FedEx and UPS, said Jack Atkins, an airfreight and logistics analyst at Stephens Inc. This suggests Amazon's delivery network would have a marginal effect on the shippers' profits, unless it becomes a direct competitor.[15]

In a recent posting on its website, Amazon noted, "Amazon is growing at a faster speed than UPS and FedEx, who are responsible for shipping the majority of our packages. At this rate, Amazon cannot continue to rely solely on the solutions provided through traditional logistics providers. To do so will limit our growth, increase costs and impede innovation in delivery capabilities. Last Mile is the solution to this. It is a program that is going to revolutionize how shipments are delivered to millions of customers."[16]

Will quality suffer?

U.K.-based online forums are rife with customer complaints on missed, late or inaccurate deliveries. And a consumer in San Francisco who now receives packages delivered by Amazon says two recent orders have repeatedly missed their delivery deadlines.

"After the first time, I asked them not to ship me anything using that service, but they did it again anyway," said the customer. "I don't want to be Amazon's test market for their new shipping idea—that's not what I am paying for."[17]

While execution of its delivery fleet hasn't been flawless, Amazon's ambitions signal that it wants to be even more integrated in its customers' lives and that the organization believes it must continually change and evolve to attain long-term success.[18]

—Compiled by Megan Schmidt, contributing editor

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SUPPLY CHAIN MANAGEMENT

SURVEY: LACK OF LEADERSHIP CAN STALL SUPPLY CHAINS

The biggest barrier to the success of an organization's sustainable supply chain practices is a lack of leadership support, according to a new report from the Association for Operations Management (APICS) that surveyed global operations executives.

About 30% of the operations executives surveyed said their organizations have a documented supply chain sustainability strategy, but only 17% of managers and those below that level in organizational hierarchies agreed with the strategy, according to the report. As a result, mid-level management is unable to take steps to drive meaningful change in supply chains.

"It is widely accepted that supply chain sustainability is a priority for many CEOs, but this is a complex business issue that brings with it multifaceted challenges at the management level," said Sharon Rice, executive director of APICS Foundation. "This study identifies patterns in the challenges that arise, helps us understand why these barriers remain and underscores how supply chain sustainability translates into measurable business value."

The report also notes that more than two-thirds of 500 supply chain executives said supply chain sustainability will play an important role in how they manage their supply chains through next year.

The 35-page report, titled "Sustainable Supply Chains: Making Value the Priority," can be found at www.apics.org/about/overview/newsroom.

KEEPINGCURRENT

Mr. Pareto Head

BY MIKE CROSSEN

ACSI INDEX

CUSTOMER SATISFACTION WITH UTILITIES FALLS

Energy utilities failed to improve customer satisfaction for the first time in eight years, according to a report released last month by the American Customer Satisfaction Index (ACSI).

Following an unusually harsh winter, customer satisfaction with gas and electric service providers was down 1.8% to an ACSI score of 76 on a 0 – 100 scale, ending a seven-year streak of consecutive gains for the sector.

"Unexpected higher cost tends to weaken customer satisfaction, but it is not the sole problem facing energy providers and their customers," said Claes Fornell, ACSI chairman and founder. "Customers not only paid more for energy this winter, but they also received less reliable service."

For more information on the rating, visit http://tinyurl.com/l2cuyu2.

ASQ JOURNAL SPOTLIGHT

QP occasionally highlights an open-access article from one of ASQ's seven other journals.

This month, read "Insights From the Baldrige Award Item-Level Blinded Applicant Scoring Data," which appeared in April's edition of *Quality Management Journal* (QMJ).

In the article, James R. Evans and Feng Mai provide further evidence for the validity of the theoretical Baldrige framework. To access the article, click on the "Current Issue" link on QMJ's website: http://asq.org/pub/qmj/past/vol21_issue2/index.html.

ASQNEWS

SR REPORT ASQ has published its sixth issue of *Pathways to Social Responsibility*. The 2014 issue explores how quality helps organizations integrate social responsibility (SR) into their business strategies. Eleven international organizations are profiled in the issue. Additional content includes articles on integrative SR, ASQ's SR body of knowledge project and integration guide, and a profile of the 2014 Spencer Hutchens Medalist. For more details, visit www.thesro.org.

TRANSLATORS NEEDED ASQ Quality Press is looking for members who can translate books, case studies and articles from English to another language, as well as reviewers to check the translations. Translators and reviewers will be compensated for their work. If you're interested, email Amber Boardman Martin of ASQ Quality Press at amartin@asq.org and include the languages you are able to translate. Also indicate any interest or expertise you have in quality, and include your curriculum vitae or résumé.

ON-DEMAND PRESENTATIONS Three sessions from May's ASQ World Conference on Quality and Improvement are available on demand for you to watch from your computer, tablet or smartphone. Speakers include Bob Pence, CEO of Freese and Nichols Inc.; Alicia Boler-Davis, senior vice president, global quality and customer experience at General Motors Co.; and Simon T. Bailey, a leadership expert. Visit http://videos.asq.org/on-demand-video-library for more details.

CULTURE OF QUALITY

ASQ PARTNERS WITH FORBES INSIGHTS ON WHITE PAPER

ASQ is sponsoring a Forbes Insights report that surveys more than 2,000 executives and quality professionals and explores the importance of the culture of quality.

The yet-to-be-released report, "Culture of Quality: Accelerating Growth and Performance in the Enterprise," will provide breakdowns by organization size, industry and by headquarters and respondent locations. The white paper also will incorporate interviews with leading corporations and experts, providing globally relevant and actionable insights.

Some preliminary key findings from the white paper include:

- Two-thirds of executives said their organizations exhibit a culture of quality, but a closer look at the key elements of such a culture (vision, values and leadership) revealed significant opportunities for improvement.
- About 62% of executives said their management supports the quality vision and values unequivocally—rising to 80% among those describing their organizations as world class.
- Nearly two-thirds of executives said they are making investments in technology to improve performance against quality objectives, with customers' needs at the forefront.

The full report also will address technology within quality initiatives—including big data and social media—and the use and effectiveness of various metrics and incentives for promoting quality goals.

The free report will be available in July at www.forbes.com/forbesinsights.

SHORTRUNS

GS1 HEALTHCARE U.S. has published an implementation guideline for using GS1 standards to address the U.S. Food and Drug Administration's new regulation for unique device identification (UDI). The guideline, titled "Using the GS1 System for FDA Unique Device Identification (UDI) Requirements," is designed for medical device trading partners, including medical and surgical manufacturers, and is available for free download at www.gs1us.org/udiguide.

THE INTERNATIONAL ORGANIZATION for Standardization's (ISO) annual report is available for download. The report includes financial statements, ISO key figures for 2013, and an updated interactive map featuring ISO members and their participation in technical work. To access a copy, visit www.iso.org/iso/home/about/annual_report-2013.htm.

Correction

Several readers pointed out errors in Figure 6 of "Virtual Voices" (May 2014, pp. 38-43). The regression analysis and Figure 6 were intended to be removed from the article and were published inadvertently. QP regrets the error.

Who's Who in Q

NAME: Saravana K. Nalatamby.

RESIDENCE: Melaka, Malaysia.

EDUCATION: Master's degree in manufacturing systems from the International University College of Technology Twintech in Malaysia.

CURRENT JOB: Calibration engineer for AUO SunPower, Malaysia, a manufacturer of high-efficiency solar photovoltaic wafers since 2010. Main responsibilities include calibration program management, clean room particle control, electrostatic discharge control and conducting measurement system analysis study for metrology equipment.

PREVIOUS JOB: His career started in 2002 as a quality assurance technician at Silterra Malaysia Inc., a manufacturer of semiconductors and wafers.

ACTIVITIES/ACHIEVEMENTS: Successfully established a comprehensive calibration program management system at AUO SunPower, Malaysia. The system uses an environmentally friendly paperless calibration form.

RECENT HONORS: He was recently named the 2014 ASQ Inspection Division Chuck Carter International Inspector of the Year.

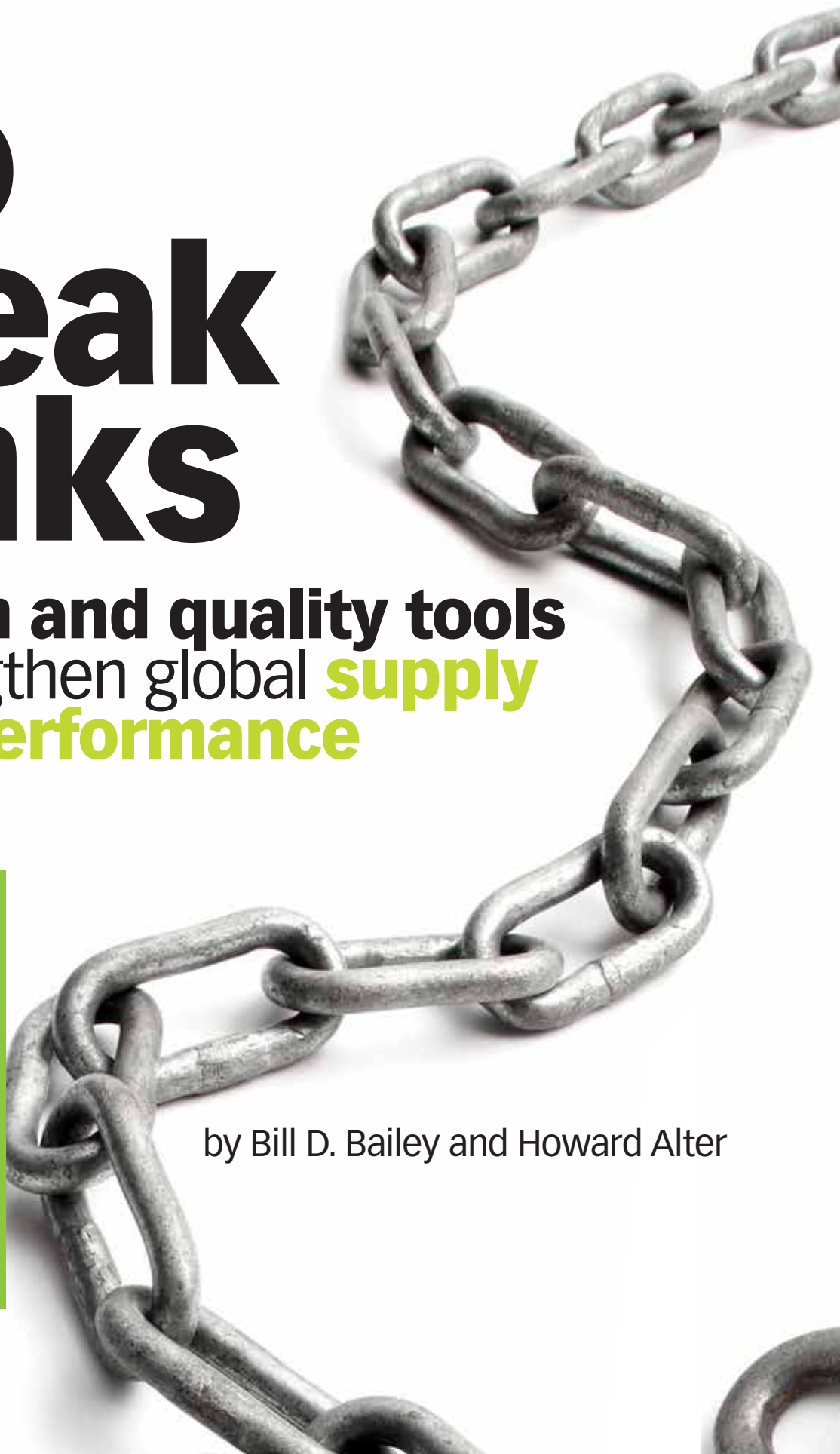
PERSONAL: Married to Sathiyah.

FAVORITE WAYS TO RELAX: Traveling and watching movies.

QUALITY QUOTE: "Customer satisfaction has always been my No. 1 priority. I continually strive to improve it." Nalatamby says that's why he likes what Mahatma Gandhi has been quoted as saying about customers: "A customer is the most important visitor on our premises. He is not dependent on us. We are dependent on him. He is not an interruption in our work. He is the purpose of it. He is not an outsider in our business. He is part of it. We are not doing him a favor by serving him. He is doing us a favor by giving us the opportunity to do it."

No Weak Links

Use **lean and quality tools** to strengthen global **supply chain performance**



In 50 Words Or Less

- When a global telecommunications organization began outsourcing manufacturing operations, it added waste to its supply chain, resulting in suboptimized performance.
- The organization employed tools such as value stream mapping, the eight rights and a plan for every part to evaluate the system to identify and remove inefficiencies.

by Bill D. Bailey and Howard Alter

DURING THE PAST 20 to 30 years, there has been an accelerated effort to move product manufacturing to the lowest-cost location. In the case of complex products and supply chains, this can lead to suboptimization of the supply chain system. Suboptimization may occur when the pursuit of the lowest piece price actually adds cost to the system.

A systems approach to analyzing an entire supply chain to determine nonvalue-added activity—some of which is introduced through the pursuit of low-cost suppliers—can help to optimize and rationalize a supply chain and result in cost savings and efficiency improvements.

Consider a case study involving Company X, a global telecommunications organization. Four years after outsourcing 80% (by revenue) of its product manufacturing, the organization faced price pressure because its manufacturing costs were higher than those of the competition. Years before outsourcing, the organization had implemented quality circles and *kaizen* events with some success. Labor costs were still too high, however, especially when competitors outsourced their products to low-cost countries, undercutting the prices offered by Company X.

Soon after implementing its outsourcing initiatives, some of the suppliers to Company X began conducting *kaizen* events that generated some cost savings. One *kaizen* event reduced labor costs on one product line by 40% with a 0.5% improvement in throughput yield. Chasing cost savings this way, however, did not address the waste built into the supply chain system.

Pursuit of the lowest-cost supplier added complexity and global distance to the supply chain. The optimization of component costs suboptimized the system, adding waste in movement and excess handling, which compounded the effect of quality problems. Quality problems, such as spring-plating issues and shipping damage, added to supply chain waste. Patchcord (a length of cable) throughput yield was calculated to be only 88.7% by the supplier.

After some research, the organization decided to use the lean tool value stream mapping (VSM), along with the "eight rights"[1] and "seven supply chain wastes"[2] to better understand its complete supply chain and to help avoid suboptimization.

Lean in the supply chain

Lean manufacturing grew in popularity in the United States throughout the 1990s. By the mid-2000s, U.S. organizations were increasingly outsourcing their manufacturing base to Asia and other low-cost labor locations. During this time, American manufacturing organizations greatly increased their supply chain investments. Because improving service response times to customers is a cornerstone of lean, many organizations saw value in applying the method to the supply chain.[3]

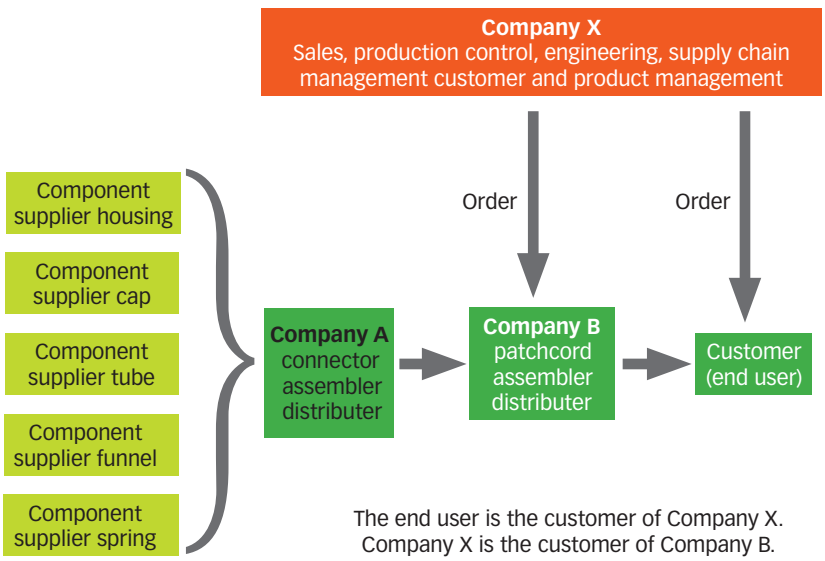
Customer-supplier relationships related to Company X's case study are illustrated in Figure 1. The supplier is responsible for purchasing components from the customer's list of approved suppliers and builds the product using the customer's processes, drawings and specifications. The supplier ships the completed product directly to the end user.

Success in a lean supply chain depends on trust between supplier and customer.[4] Lean supply chain improvement project changes often result in smaller lot sizes and reduced inventories. These are important benefits, but there is cost involved in making these changes. If the supplier is expected to absorb the costs and the customer captures all of the gains, this may threaten the sustainability of the supplier-customer relationship and of the entire supply chain system.[5]

Lean thinking leads to an understanding that in a constantly changing environment, there is always room for improvement by evaluating all the steps and removing waste.[6] It is necessary that the entire supply chain be evaluated as a system from top to bottom. The overall objective is to remove waste and its resulting cost.

After an organization decides to apply lean to its supply chain management, it must recognize that all production process steps in an organization and its supply chain are inherently tied to the end customer. In this case, Company X managed the supply chain. Its product manager defined quality and delivery requirements and price points, and acted as a representative for the end user.

Touchless supply chain / FIGURE 1



The end user is the customer of Company X. Company X is the customer of Company B.

When evaluating a supply chain, remember that "the supply chain is not just the movement of products, but the linkage of steps required to provide value" for the end user.[7] Key considerations include total cost impacts resiliency and opportunities to improve overall value for the final customer and shareholders of Company X.

Resiliency includes the mitigation of risk in the supply chain. Understanding cost impacts requires systems thinking and evaluation of the total cost of ownership, including logistics, export and customs, inventory carrying and supplier product costs. Table 1 shows a list of wastes typically found in any supply chain.[8] The list has been modified for this case study. These wastes generate significant costs in a supply chain and can be detected easily using a supply chain VSM.

Supply chain wastes / TABLE 1

Type of waste	Example	Measurement
System complexity	The use of multiple suppliers in multiple locations, and attendant inventory storage and transportation waste.	The cost of the system or the delays created by excess complexity.
Lead time	Generated by procurement when negotiating lead time with supplier or delays built into the transit process.	Cost to the system for the delays and waste of excess inventory.
Transport	Wasted effort to ship product or wasted distance in the transportation process.	Dollars wasted in transport.
Space	The space needed to transport product on a trailer or store product in raw material inventory prior to use.	Can be measured in cubic feet of space or dollar value of that space.
Inventory	Inventory beyond what is needed to serve customers and satisfy the process.	Dollar value of excess inventory and the cost of maintaining it.
Human effort	Wasted movement and motion of a worker or workers, or losses due to accidents.	Wasted time and workers' compensation insurance costs.
Packaging	The costs associated with over or under packaging resulting in waste or product damage in transit.	Cost of repeat shipping and product replacement.

Eight rights

To understand the supply chain, it is necessary to evaluate many characteristics of supplier performance. Specifically, eight characteristics of products and services in a lean environment—known as the eight rights—must be evaluated and understood.[9] The eight rights include:

1. The right product.
2. The right quantity.
3. The right condition.
4. At the right place.
5. At the right time.
6. From the right source.
7. At the right price.
8. With the right service provided.

While there isn't a one-to-one relationship between the eight rights and the seven supply chain wastes, the supply chain wastes collectively can be seen as root causes of poor performance on the eight rights.

The most common tool used to address the eight rights is a plan for every part (PFEP).[10] PFEP is used in the planning for all new parts and suppliers. It is a holistic tool in which all supply chain performance characteristics of a purchased component are documented. A PFEP allows an organization to drill down into details of the supply chain and determine optimal methods to manage suppliers so complexity can be driven out.

The eight rights are a subset of a PFEP in that they allow for the measurement of critical performance parameters of purchased parts for every shipment received. Each right is measured by the percentage of successful executions. The "perfect execution score" is derived by multiplying together percentage (proportion) of successful executions for each of the eight rights.

The percentage calculated for perfect execution can be used as a simple overall combined measurement to monitor supplier performance and be used to determine receiving inspection metrics and supplier performance scores. Remember, though, that this doesn't necessarily estimate the percentage of parts that are perfect for all eight rights simultaneously because the eight rights aren't necessarily statistically independent of one another.

A PFEP is a living document and requires updating based on the perfect execution scores. Specific actions should be taken when a supplier's perfect execution score indicates an execution problem. Table 2 (p. 18) shows the perfect execution scores before (current state) and after (future state) improvement in this case study.

Value stream mapping

VSM is used to evaluate the entire supply chain for opportunities to remove waste and cost and to mitigate risk.[11] A VSM is a visual map similar to a flowchart that shows the path and flow of physical products and electronic information in a supply chain—from raw material inception through delivery to the customer. A VSM consists of symbols that represent each step in the process, such as a storage point or transportation method. Transportation lines are detailed to show physical products and information.

The PFEP tool has been used in conjunction with VSM to create a comprehensive supply chain management evaluation tool. The PFEP tables (Table 2) provide measurements of supplier performance for the eight rights. When poor performance is identified, VSM is used to identify the seven wastes, which may be the cause of the poor supply chain performance.

Plan for every part performance / TABLE 2

Current state

	Connector	Spring	Connector	Connector assembly
Lead time	21 days	6 weeks	8 days	**25 days**
Average inventory	25k	200K	45k	33k
Batch size	5k	300K	5k	5k
MoQ	5k	300K	5k	10K
Perfect execution	**99%**	**55%**	**98%**	**89%**
Right quantity	100%	100%	100%	100%
Right product	100%	100%	100%	99%
Right place	100%	100%	100%	99%
Right time	100%	80%	98%	98%
Right quality	99%	95%	100%	98%
Right source	100%	100%	100%	99%
Right cost	100%	90%	100%	97%
Right service	100%	80%	100%	99%

Future state

	Connector	Spring		Connector assembly
Lead time	21 days	2 weeks		**8 days**
Average inventory	25k	100K		10k
Batch size	10k	100K		5k
MoQ	10k	300K		5k
Perfect execution	**99%**	**~100%**		**95%**
Right quantity	100%	100%		100%
Right product	100%	100%		100%
Right place	100%	100%		99%
Right time	100%	100%		98%
Right quality	99%	100%		99%
Right source	100%	100%		100%
Right cost	100%	100%		100%
Right service	100%	100%		99%

MoQ = minimum order quantity

Plan-do-check-act

The plan-do-check-act (PDCA) cycle also can be used in conjunction with PFEP and VSM to evaluate a supply chain and remove waste. The plan phase begins when the PFEP and current-state VSM are created by a cross-functional team representing all departments involved with supply chain management. If a perfect execution score does not exist, it can be established based on existing data, such as on-time delivery and receiving inspection metrics.

The team performs root cause analysis of suppliers that exhibit a poor perfect execution score and evaluates the VSM to identify potential wastes. Some areas in which waste might be found include:

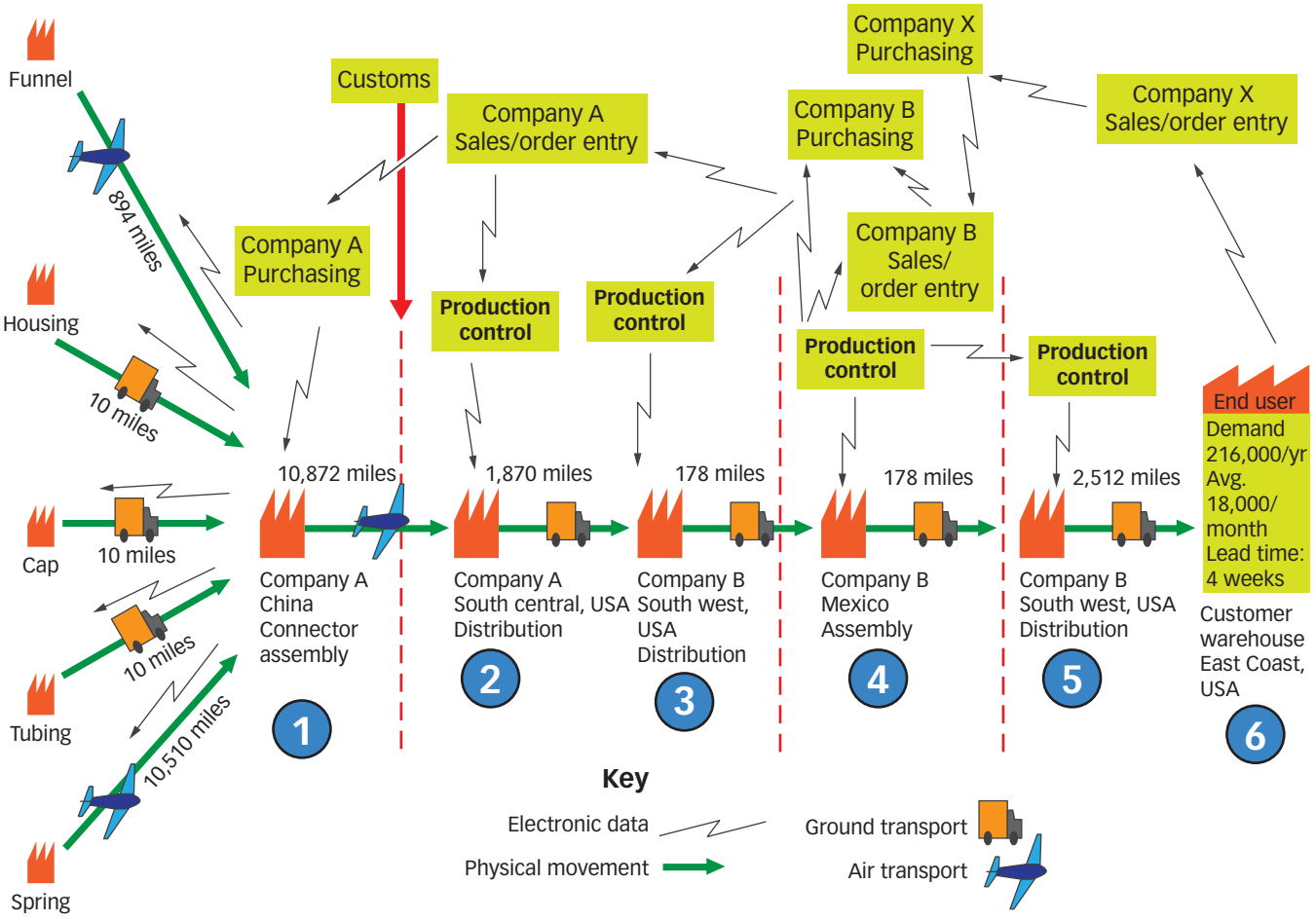
- Distances between suppliers and customers, including international barriers.
- Modes of transportation.
- Warehousing needs.
- Inventory quantity and costs.
- Lead times.
- Container costs for overseas shipments.
- Special packaging needs.

In the do stage, the team selects improvements to be implemented based on estimated cost reductions (to be achieved by minimizing transportation) and risk. The team creates a future-state VSM based on the selected improvements.

The check phase includes a review of the plan and do phases. The cross-functional team evaluates each proposed change to verify potential cost savings and ensure changes will not adversely affect product and service quality, or add complexity or other wastes into the system.

The act phase is used to implement the selected changes and measure the results. These changes may initiate the qualification of new suppliers and would prompt communication of new requirements through

Current-state value stream map / FIGURE 2



the supply chain as needed. Data are typically gathered and used to revise the eight rights, perfect execution and receiving inspection, and to verify supplier performance targets.

Company X case study

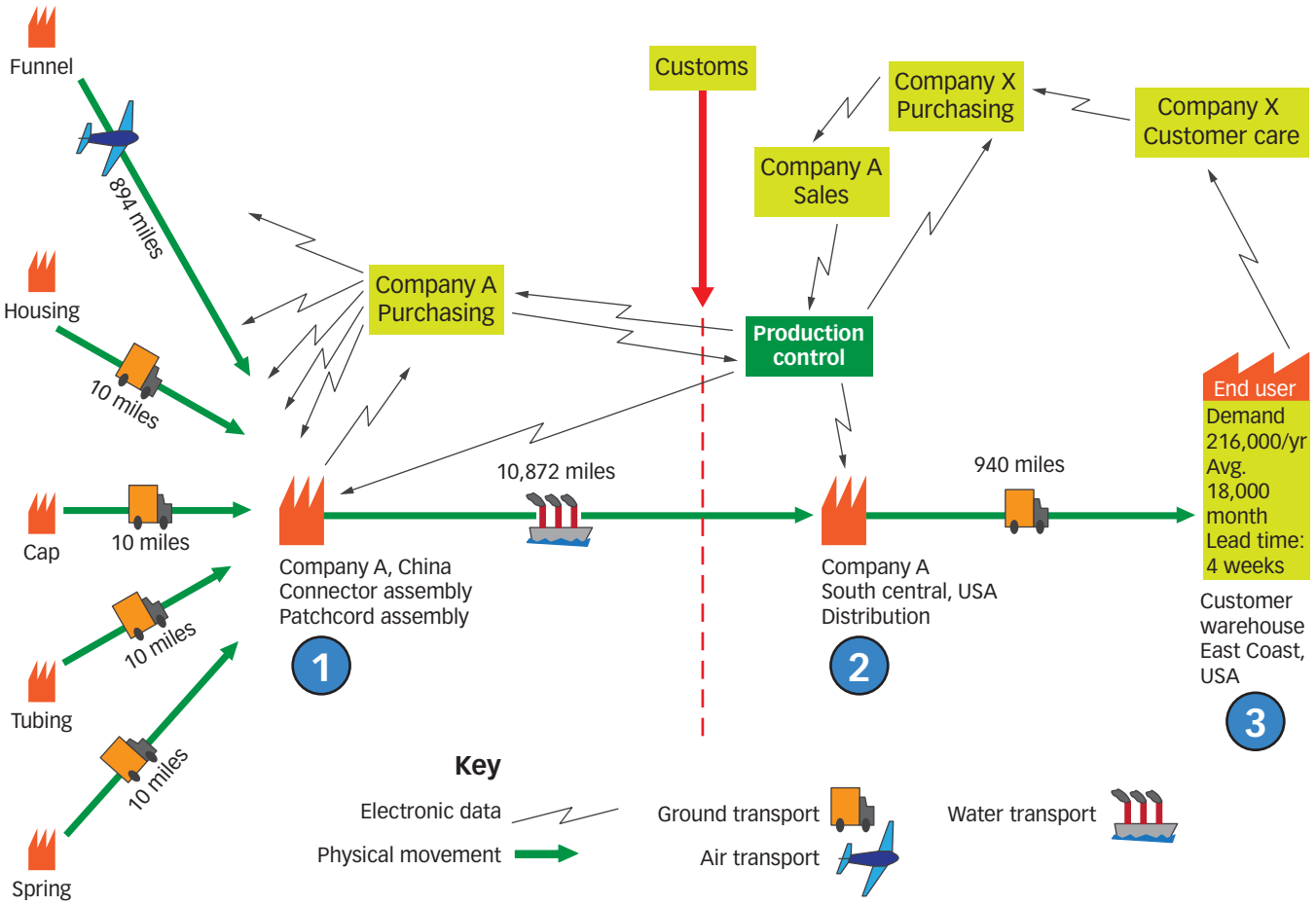
When Company X launched its improvement project to drive waste out of its global supply chain, it was operating a touchless supply chain. This is one approach to global sourcing and can be explained as: "Rather than actually touch the product, large brands will simply orchestrate all the moving parts that comprise their supply chain."[12]

A touchless supply chain was developed by Company X during a previous outsourcing effort. Company X handles information and manages its suppliers, but never takes possession of the product. Company X places an order with Company B.

Value stream map improvements / TABLE 3

Improvement	Status	Benefits
Qualify a new spring supplier that is in close proximity to the connector assembly plant.	Implemented	Saved 10,500 miles of freight (for each trip, every six weeks) for springs. Improved "perfect execution" score from 55% to nearly 100%.
Qualify the connector assembly plant to assemble the final product: patchcord assembly.	In process of being implemented	Saved an additional 3,628 miles of transport costs. Allowed the assemblies to be built using lower cost labor. Saved 10% on transportation costs. Saved on customs fees and delays into and out of Mexico. Saved on transactional fees and administrative fees by eliminating one supplier.

Future-state value stream map / FIGURE 3



Company B extends the order to upstream suppliers (Company A) and also ships directly to the end user (Figure 1, p. 16).

The current-state VSM (Figure 2, p. 19) shows the touchless supply chain for a connector assembly made up of a connector and a final assembly patchcord (depicted in the illustration). The patchcord is the finished product delivered to the end user. The current-state VSM (Figure 2) shows six major steps in the supply chain.

Step one is the connector assembly process performed in China by Company A. Company A used five local Chinese suppliers to provide the components for the connector assembly process. In step two, the assembled connector was shipped to the Company A distribution center in south central United States. The Company A distribution center then shipped the connector to the Company B distribution center in south west United States (step three), which sent it to a contract manufacturer in Mexico (step four) for final assembly into the patchcord.

After the finished product (the patchcord assembly) was assembled, it was shipped back to the Company

Patchcord assembly

Spring and tubing are hidden by housing.

B distribution center in south west United States (step five). In step six, the patchcord assembly was shipped to the end user's warehouse on the East Coast.

The current-state VSM (Figure 2) shows the flow of physical products and electronic data. The connector component suppliers are on the far left of the VSM, and the end user is on the far right. This arrangement reflects the flow of materials. The flow of information goes from the end user to Company X to Company B and back through the supply chain. The shipping distance in mileage is shown beneath the truck and airplane symbols. Note the map is not to scale.

Table 3 (p. 19) shows supply chain improvements identified through the VSM process. The new supply chain process contains only three major steps instead of six. The connector and patchcord assembly are performed in China by Company A (step one). Company A sends the patchcord assembly to its warehouse in south central United States (step two) and on to the end user on the East Coast (step three). The new process completely eliminates Company B and three of the six steps.

Although sourcing the patchcord assembly to Company A may not have resulted in the lowest cost for that particular step, the reduction in complexity has resulted in significant improvements in the system. The future-state VSM (Figure 3) shows these improvements. The overall savings between the current and future VSMs are 14,298 miles annually.

The poor supply chain performance for the spring was a result of the compound effects of the lack of perfect performance on time, quality, cost and service. The perfect execution (Table 2) for the newly sourced spring improved from 55% in the current state to nearly 100% in the future state. The connector assembly improved from 89 to 95%. Total lead time was reduced from 96 to 43 days. Connector assembly quality increased from 98 to 99%, and performance on right cost improved from 97 to 100%. In addition, the 14,298 miles saved has an impact on the organization's overall carbon footprint.

Future improvements planned

Quality and delivery levels for Company X also can be improved through less product movement, and future improvements will include reduced inventory levels. A next step in lean implementation might be a *kanban* system to manage product flow. *Kanban* is a visual or automatic signal system that triggers replenishment of materials.[13] This will facilitate a change to a pull rather than a push system to align production more closely with customer requirements, and further eliminate waste and reduce work in process inventory.

These savings will be calculated after the improvements have been qualified and implemented. Additional improvements, including expanding this approach to other products, are being developed.

This case study demonstrates the value of systems thinking in supply chain management. Keep in mind that this study focused on a single assembled product, so it represents a small sample of the entire Company X supply chain. What the organization learned from this project can be leveraged across all its product offerings for greater efficiencies and even greater savings. QP

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Need for

Developing a fast and flexible supply chain that **leaves competitors in the dust**

In 50 Words Or Less

- Consumers in the global marketplace move fast. To remain relevant and competitive, so should manufacturers and suppliers.
- Achieve rapid delivery and speed to market with processes, mechanisms and tools that optimize supply chain performance.
- Relationships should take a front seat as organizations balance internal and external efforts to power innovation.

by Karen Spencer
and Steve Helfer

Speed

ORGANIZATIONS CANNOT ACHIEVE supply chain quality unless they understand how their customers perceive quality. The global marketplace is creating new challenges for manufacturers and suppliers in meeting customer expectations. Customers want products and solutions more quickly. Suppliers, however, are affected by forces from all directions and must have a supply chain that executes on all quality management metrics.

While there are fundamental and essential aspects of quality management in supply chains, there also are instances when specific areas may reflect distinct, unique characteristics and needs of an individual customer operating in a specific and specialized market segment.

Organizations must focus on key indicators and achieve optimal performance levels. They must define quality as it relates to customers and modify quality to achieve and sustain quality levels that maximize supply chain performance and quality management.

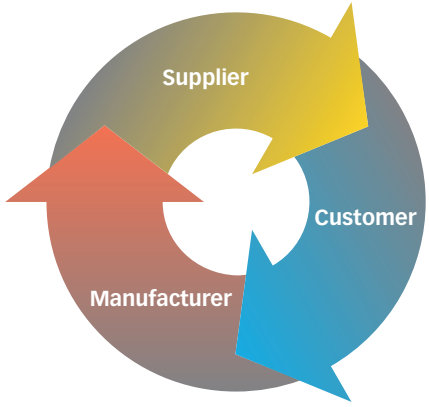
Current considerations surrounding supply chain quality management include:

Sound processes and systems. Quality in product production and the production process is obtained by having a flexible system to create, organize, release and document manufacturing details, processes and work instructions.

The system should support cross-functional teams as they assess:

- The route the part will travel during production.
- The gages and tooling needed and their availability.
- Whether the customer has specified material and testing requirements.
- Whether outside processing is needed. If so, what the lead-time is and whether the supplier is an approved one.
- Whether the customer requires that significant characteristics be checked and documented. If so, what sampling plan will be used?
- Whether and how the product will be packaged and shipped.
- Whether all specifications are called out on the purchase order.

Communication flow / FIGURE 1



Speed. Speed is a supply chain performance measurement that customers increasingly require and associate with quality. Rapid response is essential to attaining and retaining customers and is a key element of speed to market, especially in a business-to-business context. Achieving this quality indicator helps manufacturers and suppliers attain and retain customers.

Rapid delivery and speed to market can be achieved with proper planning. Organizations must have skilled employees who can react quickly and make decisions. As an employer, you must ensure employees have the tools and resources they need to make quick decisions.

Maximized internal productivity. Maximizing internal productivity is impossible unless organizations have equipment to produce a quality product. Keeping machines in top-notch shape is as important to the machine as it is to the organization.

Preventive maintenance must be performed per the manufacturer's recommendation. Downtime on a machine means it is not producing products and the organization is not making money.

Error-free shipping. Flawless shipping is easily achieved if an organization has properly trained employees. Detailed instructions also must be available for employees to refer to.

Detailed instructions should state special handling, packaging or care. They should specify what must be included in the shipment to the customer. Many customers require statistical process control data, certifications and layouts.

Receiving the right product at the right time with the right paperwork. We have all received an expedited shipment and found it is not what we ordered. Accuracy is critical and central to the entire supply chain process and is directly related to speed to market.

If certification does not accompany the delivered product, the customer may have to return the product to the supplier and request it. Often, this inconvenience will delay shipping the products to the next customer in the chain. To ensure speediness, eliminate problems by training and communicating with suppliers. The purchase order that is sent to them must include all requirements.

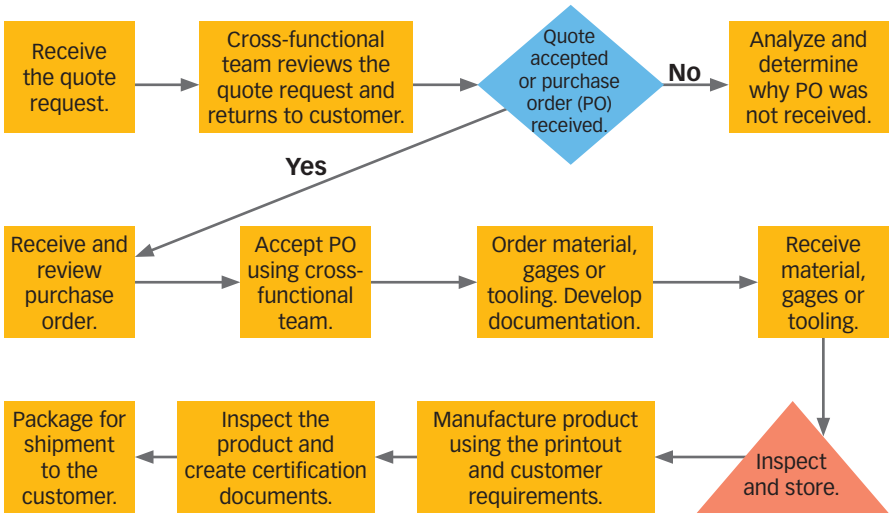
Establishing and maintaining collaboration. Establish a team of internal and external experts to help improve products, refine processes and cut costs. Suppliers and customers can collaborate with product makers and bounce ideas off one another. A good relationship among manufacturers, suppliers and customers can speed up

the process from design to delivery. The communication flow must not stop (see Figure 1).

Alignment with customer requirements. Know exactly what customers want and when they want it. Purchase orders and printouts will help communicate requirements. Figure 2 shows a sample project request.

Regulatory compliance. Many customers have specific regulatory requirements that are communicated to suppliers via purchase orders. During contract review, customers and suppliers should ensure regulations can be met. For example, U.S. International Traffic in Arms Regulations are a set of regulations that control imports and exports and are critical in supply chain matters associated with defense-related services.

Request for shipping quote / FIGURE 2



Hurdles to overcome

If your supply chain is not effective and efficient, it will not successfully launch products or win the market. Organizations, however, cannot be experts in all fields, but the pressure to increase sales drives organizations to launch new products at unprecedented rates. Ideas for new products, which can develop at any point in the supply chain, are referred to busy engineering groups that are unable to deliver new designs at the required speed and reliability to capture market opportunities. Overcoming these hurdles, however, is imperative for success.

The designs must be built into prototypes and moved quickly to production because building prototypes conflicts with monthly production and sales dollars. Suppliers sometimes fall short. When managers focus resources on monthly results and local optima, prototypes fall behind schedule.

Getting off track could cause the sales force to lose customers. Competitors may sweep into the market and materialize the great idea. Here's what organizations can do to prioritize in-house new product development:

Don't lose focus. Distractions can break supply chains. Having too many projects or products to develop at one time can stunt progress. Resource conflicts may stall processes. Engineers and machinists who are constantly pulled off projects and prototypes to firefight day-to-day issues on the shop floor are unable to fully concentrate on product development.

Be a one-stop shop. In-house equipment is often not designed to take prototypes to production because most production machines lack visibility and flexibility and are purchased for a predetermined production family.

In addition, determining how much equipment is needed is challenging. The capacity of a system must be flexible, however, and meet the high demands on delivery. Unfortunately, one day a team might be sitting around doing nothing, and the next day it might need two or three five-axis machines to keep pace with demand.

Machinery, however, must be 100% dedicated to the process to ensure availability. Organizations may need more than simple lathes and mills with production-slowing setups. Machines need to be beyond simple computer numerical controlled (CNC) lathes and mills because the time to setup and re-setup machines will slow the process. Organizations can ensure process output is fast and correct by using five-axis CNC machines with live tooling and several cutting tools. Rapid casting also demands pull with suppliers who keep stock of the material you require.

Align the team. Staff may not have time nor skills to support anything but current production. Line managers may focus on meeting daily, weekly and monthly shipping goals—not on the long-term measurements. Build a cross-functional engineering team with competencies in design, materials, tooling, machining and quality.

Benefits of outsourcing

Because building and training qualified staff can take years, and updating facilities can cost millions with no guarantees of return on investment, many organizations turn to supply chain partners to help them build what they can't complete in the required time.

Developing a partnership with an organization that has the team and equipment in place to make a project a success can be an attractive opportunity. These partnerships can curb the costs of lost business caused by late products, can allow an organization to avoid years of team training, and can eliminate the capital costs of building an operation and purchasing equipment. Avoiding idle time when projects are slow or nonexistent is another benefit of working with an outside team.

What stops some organizations from taking this path is the fear they will lose control of the project or product design. Furthermore, when control of the lead time of the project is in the hands of someone else, the biggest fear is that the partner's service costs are high.

The benefits of partnering with a prototype-to-production supplier, however, include:

- Project control increases because the correct partner has the resources to support the project.
- The partner works one-on-one with designers to ensure the output meets the requirements.
- Lead-times are reduced because the partner is a specialist and resolves issues quickly.
- The partner has subtier suppliers that respond and deliver more quickly and efficiently than anyone else.

Supplier selection criteria

Missing the market or being late because you're working on competency and capacity issues will often cost you more in the long run than the costs to outsource, which are usually pennies on the dollar. Outsourcing gives organizations flexibility to pay as they need resources.

If an organization opts for an outside supplier to help it meet supply chain quality measures, it shouldn't make its selection hastily. Here is a short list of what to look for and what to ask when outsourcing:

- Partners must fill gaps and be flexible. Ask how much open capacity there is.
- Partners must have a proven track record. Check references.
- Partners must think, breathe and live what the customer needs. Take a tour and see the operation in action.
- Partners must have pull with other contractors for rapid subsourcing. Ask about the lead time any subsourcing will require.
- Partners must be the fastest available. Outsourcing to save 10 to 15% on hiring could cost thousands of dollars in market losses in the end.
- Partners must be stable and secure. Consider factors such as sustainability, growth and years in business.
- Partners must have a high quality mindset and inspect every part that goes out the door. Look for international quality system certifications, such as ISO 9001 or AS9100, and regulatory compliance.
- If necessary, partners must understand how to take 3-D models to production.
- Partners must employ competent and process-oriented staff. Talk to workers on the shop floor who do the programming and machining, and ask questions about the process.
- Partners must operate as a one-stop shop and take an organization's idea from prototype to production.

Effective supply chain management is essential for any organization attempting to attain excellence. A manufacturer, for example, cannot achieve quality in its supply chain unless the organization thoroughly understands what quality means to its customers.

Sometimes, it's necessary for an organization to retain a partner to help it achieve quicker lead times and lower costs and to ensure quality throughout the entire supply chain management process or in specific areas. Quality itself may be defined differently from one organization to another, but certain tenets of quality in a supply chain remain fundamental and essential. All organizations that focus on speed—a fundamental supply chain principle and quality metric—will reap rewards. QP

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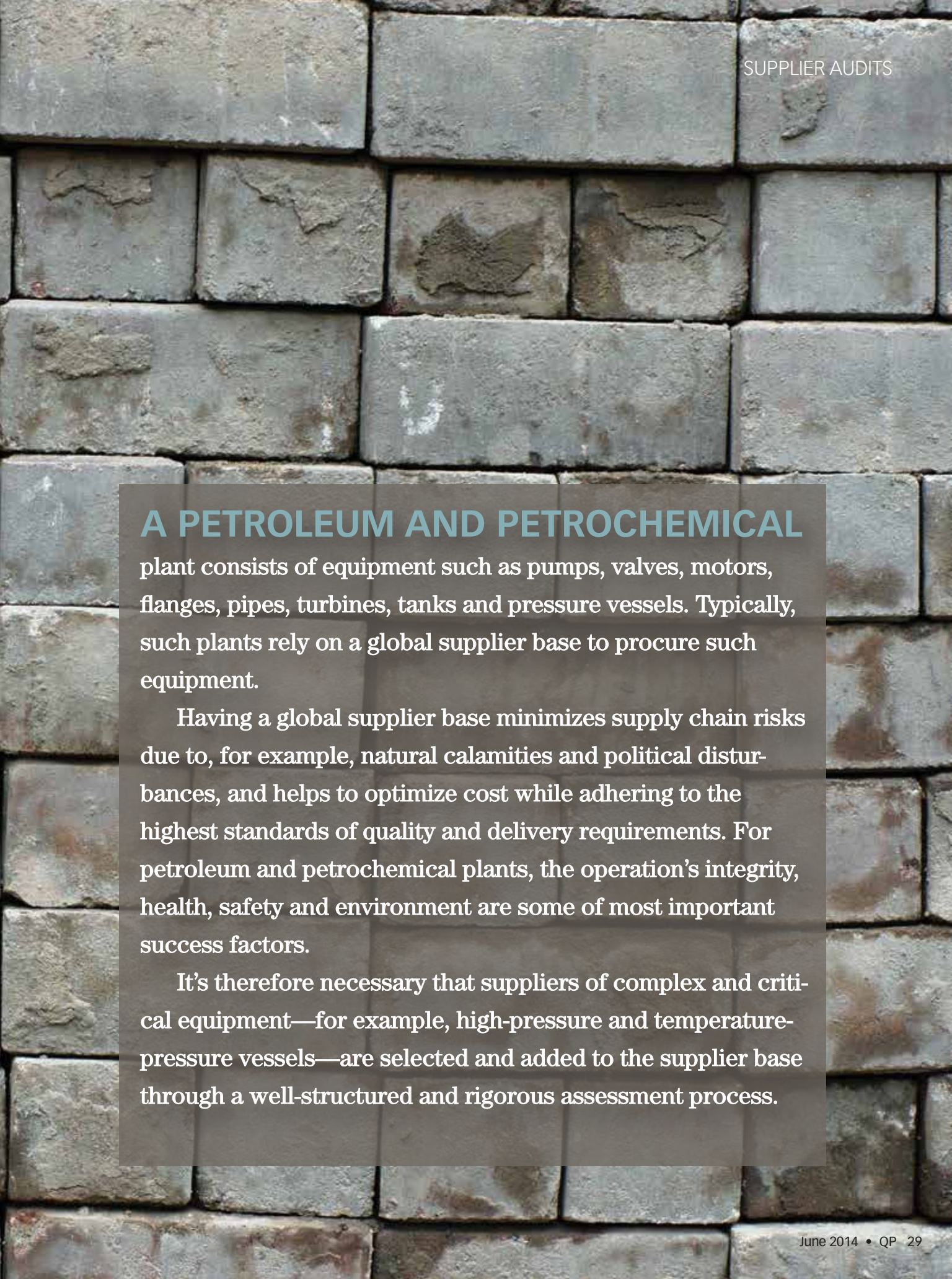
Solid BASE

by Afaq Ahmed

In 50 Words Or Less

- Building a successful business in today's volatile, unpredictable global marketplace hinges on finding reliable, qualified equipment suppliers.
- Before you decide to forge specific partnerships, you must thoroughly assess the suppliers to ensure they are competent and reliable.
- A checklist technique incorporating important internal process factors can help assess suppliers.

Improve supplier assessments by **incorporating process factors** into checklists



A PETROLEUM AND PETROCHEMICAL plant consists of equipment such as pumps, valves, motors, flanges, pipes, turbines, tanks and pressure vessels. Typically, such plants rely on a global supplier base to procure such equipment.

Having a global supplier base minimizes supply chain risks due to, for example, natural calamities and political disturbances, and helps to optimize cost while adhering to the highest standards of quality and delivery requirements. For petroleum and petrochemical plants, the operation's integrity, health, safety and environment are some of most important success factors.

It's therefore necessary that suppliers of complex and critical equipment—for example, high-pressure and temperature-pressure vessels—are selected and added to the supplier base through a well-structured and rigorous assessment process.

One of the major steps in conducting such assessments is preparation, It is essential that adequate time is spent planning. There are four main phases in assessment preparation:

1. Reviewing quality management system (QMS) documents.
2. Establishing an assessment plan.
3. Assigning responsibilities to assessors for specific processes of QMS.
4. Preparing documents needed for the assessment. These documents include a checklist for asking questions based on agreed-on criteria—for example, ISO 9001—and recording assessment observations.

A checklist developed using only ISO 9001, however, may not be adequate. Conducting a thorough supplier assessment must allow the assessor to take a deep dive into important process factors that are significant to quality, such as input, people, resources, information, controls, performance measures, quality objectives, output and others.

There's a technique to prepare a methodical and thorough checklist by following the organization's process steps. Using a case study of a pressure-vessel manufacturing process will explain this technique further. This approach, however, can be applied to assess suppliers that contribute to any manufacturing or service process.

The manufacturing process

The first step is to understand the pressure vessel manufacturing process. The process flow diagram in Figure 1 shows the major steps of manufacturing a pressure vessel.

Select an assessment sample: After reviewing the manufacturing process, select the assessment sample—that is, subprocesses the assessment should focus on. For selection and approval of a new supplier, the entire process from start to finish (from receiving inspection to final inspection) should be assessed.

For a surveillance-type assessment of an existing approved supplier, critical subprocesses of the process, such as welding, may be selected for the assessment. For the sake of simplicity in this case study, the subprocess of sheet metal cutting (step two highlighted in Figure 1) is selected for the assessment. Cut components are used to form the shell of a pressure vessel and various other parts of the vessel.

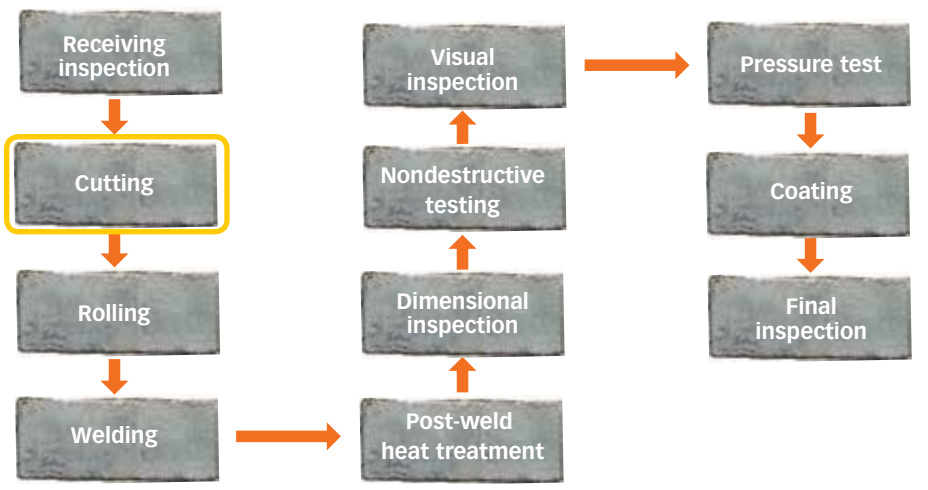
Identify process factors: Next, identify process factors that can significantly affect the quality of the cutting process—for example, inputs, controls, performance measures, output and others (Figure 2). These are some of the factors an assessor will focus on.

Identify elements of process factors: In this step, look more deeply into process factors of the selected subprocess and identify elements that can affect quality. For example, some of the elements of input that can affect quality of the end product are the cutting machine, steel plate, cutting procedure and operator capability (see Table 1).

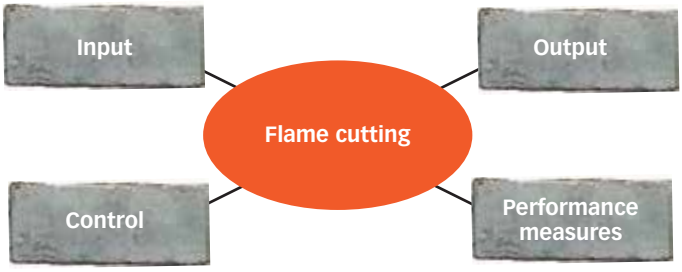
Identify quality requirements: Now identify the quality requirements for each identified element (machine, steel plate and procedure) that can affect the end product's quality. The machine's capability and condition can affect cutting process quality.

A well-maintained machine will produce high-quality components required for the assembly of a pressure vessel without unplanned downtime. The quality of a steel plate—such as its thickness, physical and chemical properties—plays a significant role in performance of the pressure vessel. Other quality require-

Simplified process flow diagram of pressure vessel manufacturing process / FIGURE 1



Examples of significant process factors for cutting operation / FIGURE 2



Process factor elements / TABLE 1

Process factor	Elements
Cutting	Machine
	Steel plate
	Procedure
	Operator capability

ments are the availability of updated procedures and the competency of the operator.

Map quality requirements to ISO 9001

Next, map the quality requirements to relevant ISO 9001 clauses. The cutting machine capability can be mapped to ISO 9001:2008, clause 7.5.1, which requires the production be carried out under controlled conditions. One of the controlled condition requirements stated under clause 7.5.1c is the use of suitable production equipment.

Steel plates are generally purchased by the pressure vessel's manufacturers. The quality requirements of steel plates, such as its thickness and material properties, can be mapped with ISO 9001, clause 7.4.3, which requires the organization to inspect and ensure the purchased product meets specified purchased requirements.

ISO 9001, clause 4.2.3, requires control of QMS documents. The cutting procedure, which is a QMS document, can be mapped to clause 4.2.3. Similarly, the competency of the operator can be verified through the individual's training records, which can be mapped with ISO 9001, clause 6.2.2.

Identify supporting information: What supporting information must the assessor include in the checklist questions? To inquire about the cutting machine capability and maintenance, for example, the assessor must know the cutting machine number and its location on the production floor (a manufacturer may have several of these machines).

Similarly, for an assessment question pertaining to the quality of the steel plate, the assessor must have identification information about the steel plate, such as the heat number and job number. To verify whether the procedure is a QMS controlled document, the assessor must know the cutting procedure number, revision date, approving authority and approval date. For questions related to operator competency, the assessor must know his or her employee number.

Develop the checklist

Based on the information gathered, now it's time to develop the checklist for the pressure-vessel manufacturer assessment. For the cutting machine, which is one of the input components, the quality requirement is that the machine be capable of cutting a steel sheet of required thickness. Therefore, an appropriate question to ask is: How thick a steel sheet can the machine cut?

Questions to ask the supplier regarding the maintenance of the cutting machine could be: Is the maintenance plan developed? Is maintenance done according to the plan? Table 2 (p. 32) provides a list of some of the pertinent assessment questions concerning the quality requirements of the input process factor.

Identify links: An organization consists of a chain of processes that interact with one another to transform input into meaningful output. These processes are linked to achieve certain objectives. Assessment results can be more effective if the assessor identifies interdependencies of processes and tests them during the assessment. This technique allows an assessor to identify links between processes and to carry out interdepartmental assessment.

The next step is to identify links of the cutting subprocess with other processes and departments of the

Checklists are useful as long as the temptation to merely **check off bullet points on a list is avoided.**

assessed organization. For example: Is the receiving inspection of steel plates carried out by the receiving inspection section of the quality department? To find out, the assessor must visit the receiving inspection section of the quality department. To answer questions regarding the maintenance of the cutting machine, the assessor must visit the maintenance department. To answer questions regarding the operator's competency, the assessor must visit HR.

Expand the checklist: In this step, the list of assessment questions can be expanded. Questions regarding the maintenance of the cutting machine, for example, can be detailed to include:

- Are the maintenance technicians' education, skills and experience records maintained?
- Are the maintenance technicians' training records maintained?
- Are tools to carry out maintenance available?

Similarly, questions related to the quality of the steel plate can be explored further: Was the steel sheet purchased from an approved supplier? The question regarding control of procedure also can be expanded: Was the cutting procedure approved? Is the procedure current?

More specific questions based on manufacturing procedures and instructions can be added to the list. Is the material test report available? Do the steel plate properties meet customer specifications? Are welding consumables stored per manufacturer recommendations? Are welding procedure specification and procedure qualification records available?

As noted earlier, a process has many components, such as control and measurement. In previous steps, only questions pertaining to the input component were identified. In this step, questions related to other components are explored: Are the voltage, current and speed of the welding head controlled? Is welding done in a controlled environment? Are dimensional and visual inspections of the shell done? Is the shell inspected after welding?

If all steps of this technique are adhered to, the final checklist may look something like the example in Table 3.

Assessment questions / TABLE 2

Subprocess: Cutting		Process factor: Input	
Assessment questions	**Supporting information required**	**Input element**	**Quality requirements ISO 9001:2008 clause**
1. What is the maximum thickness of steel that the machine can cut? 2. Is the maintenance plan developed? 3. Is maintenance done according to the plan?	Cutting machine number and location.	Cutting machine	Capability clause: 7.5.1 Maintenance clause: 6.3
4. Is receiving inspection of steel plates done?	Steel plate identification (heat number and job number).	Steel plate	Quality (thickness, physical/chemical properties) clause: 7.4.3
5. Has a document control procedure been developed?	Cutting procedure number, revision date, approval authority and approval date.	Procedure	Approved and latest revision clause: 4.2.3
6. Are operator education, skills and experience records maintained? 7. Is the operator's training record maintained?	Operator information (for example, employee number).	Operator	Records of operator competency and training clause: 6.2.2

Making checklists more valuable

This assessment technique can make assessing suppliers of critical and complex equipment much more valuable because it allows an assessor to carefully examine important process factors that can significantly affect quality.

This technique also allows for more efficient assessments to take place. The assessor can ask department personnel all pertinent questions in one visit. If the assessment is conducted using a checklist based on ISO 9001 clauses (4, 6 and 7, for example), an assessor may need to make several trips to the quality department to ask questions regarding:

- Document control of cutting procedure (ISO 9001, clause 4.2.3).
- Nondestructive test inspector certification (ISO 9001, clause 6.2.2).
- Receiving inspection of steel plates (ISO 9001, clause 7.4.3).

Checklists are useful as long as the temptation to merely check off bullet points on a list is avoided. Also, checklists reduce the time for preparing assessment documents. It should be acknowledged that organizations deliver products and services through a network of interdependent and interlinked processes. Through the use of this technique, a simple checklist can be expanded and reorganized along the lines of the process.

Another advantage of this technique is that it allows an assessor to identify links among different processes of the organization to carry out interdepartmental assessment, thus revealing deficiencies in the system that may occur due to the standalone nature of departments. These deficiencies may be caused by miscommunication, misinterpretation, inadequate information exchange or the lack of training of the personnel. QP

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Final checklist / TABLE 3

Assessment questions	Interaction of production process with other processes/functions
1. What is the maximum thickness of steel that can be cut?	Manufacturing engineering
2. Is the maintenance plan developed? 3. Is maintenance done according to the plan?	Maintenance
4. Is receiving inspection of steel plates done?	Quality
5. Has a document control procedure been developed?	Quality
6. Are operator education, skills and experience records maintained? 7. Are operator training records maintained?	Human resources
8. Is the dimensional inspection report available? 9. Is the steel plate thickness as per the customer requirement? 10. Is a material test report available? 11. Does the steel meet physical and chemical properties as required by the customer specifications?	Quality
12. Are welding consumables stored as per manufacturer recommendations?	Store room
13. Are welding procedure specifications (WPS) and procedure qualification records available?	Welding
14. Are maintenance technicians' education, skills and experience records maintained? 15. Are maintenance technicians' training records maintained?	Human resources
16. Are tools to carry out maintenance available?	Maintenance
17. Were steel sheets purchased from an approved supplier?	Purchasing
18. Was the cutting procedure approved? 19. Is the procedure current?	Quality
20. Is voltage, current and speed controlled during welding as per approved WPS?	Welding
21. Is the welding environment controlled?	Welding
22. Are calibrated gages used for inspection of rolled shells?	Quality
23. Are nondestructive testing inspectors certified?	Quality
24. Is the hardness testing machine calibrated?	Laboratory
25. Is the baking procedure for welding electrodes available?	Welding
26. Is dimensional and visual inspection of the shell done?	Quality
27. Is the welded shell inspected?	Quality

Insurance Policy

Secure document control **starts with a well-planned** enterprise content management system

by William Minckler

THE YEAR 2013 revealed significant malfunctions in enterprise content management (ECM) operations, which led to prominent news items about the failure of quality management.

Examples include the Wiki Leaks debacle in which Sgt. Chelsea Manning used Microsoft SharePoint to extract and provide thousands of key documents to the public; former U.S. National Security Agency (NSA) contractor Edward Snowden disclosed millions of classified NSA documents through several media outlets; and at the end of the year, Target announced the security breach of up to 40 million credit and debit card accounts.

Events in 2014 showed that planning, securing and managing ECM systems continues to be a relevant topic. Reports surfaced in February of a data breach at the University of Maryland that exposed 300,000 applications containing personal information of enrollees dating back to 1998.

While national security and millions of financial accounts may not always be at stake, every organization holds customer data, legal documents and organizational knowledge that need protection. Using a quality-centric approach, the Ohio Department of Job and Family Services (ODJFS) in 2012 embarked on an initiative to create an ECM system to manage, safeguard and accelerate the use of key informational assets.

In 50 Words Or Less

- Enterprise content management (ECM) systems can enhance document management to reduce risk and meet customer needs.
- A government agency embedded quality principles into the design and deployment of an ECM system for 12 offices.
- The process included assessing needs, engaging a cross-functional team, creating a deployment model and measuring success.

As a government agency, ODJFS is faced with hundreds of thousands of documents within its systems. On any given day, thousands of documents stream through the departments in a continual state of change. These documents span the entire gamut of operations: services rendered to taxpayers, contracts, agreements, vast collections of procurement documents, policies and procedures, operational documents, infrastructure designs and entire training systems.

With these documents come important quality responsibilities: reliability, security, suitable storage, proper quality reviews, collaboration and dissemination of information within the organization, managed changes to documents, and the proper retention and destruction of electronic documents.

In a rapid application development approach, a team of seven was tasked with designing, constructing and implementing an ECM solution for 12 offices across ODJFS. The one-year project was planned to span three phases. Table 1 illustrates the phases and corresponding outputs. A unique hallmark of this project was to embed quality into the inherent design, development and execution of the system.

Phase one: planning and designing

At a high level, ODJFS understood the need for the agency to improve its ECM, so the enterprise architecture group of the agency scanned the marketplace for technologies. Evaluation criteria for the technologies are listed in Table 2.

Based on the criteria, the organization architects recommended Microsoft SharePoint 2013.[1] From the project's inception, selecting a high-quality technological solution proved to contribute significantly to the success of the project by offering a well-tested, supported and reliable base platform.

With organizational goals explicitly stated and a viable product selected, the chief information officer of enterprise architecture formed a project team. A cross-functional project team was designed with two purposes in mind:

1. Specialists from differing domains would ideate and enhance the quality and adoption of the solution.
2. A diverse team would reduce risk because the members would view the development process with divergent, broad perspectives and expertise.

Building a team of experienced and cross-functional members contributed to the quality of the project. The seven-member team included:

- Executive project sponsor.
- Senior project manager.
- Senior SharePoint program manager.
- Senior SharePoint architect.
- Three technical programmers and developers.

Five team members were provided through internal resources within ODJFS. Two team members—the SharePoint-specific resources—were procured from an external, private-sector consulting agency.[2] Combining public and private sector skills into a single team proved to provide an optimal blend of experience and perspectives.

Identifying the organization's stakeholders also played a significant role. "Quality" was defined and would be measured by building the right solution that would meet the needs of the internal customers. Additionally, "stakeholder" was defined as anyone who would be affected by the project—either positively or negatively.

The team therefore identified a broad, representative range of stakeholders to assess operational goals and provide true value. Stakeholders included each government office that offers services to public clients and internal departments, such as legal, information systems, HR, communications, financial and fiscal monitoring, and policy and administration.

Master project plan / TABLE 1

Phase	Duration	Activities
1. Plan and design enterprise content management (ECM) solution.	3 months	• Select the current SharePoint 2013 technology. • Form project team. • Identify high-level stakeholder requirements. • Assess high-level agency and state requirements. • Identify IT industry best practices. • Plan the service platform features and architecture.
2. Build ECM solution.	2 months	• Build hardware service platform. • Install software, configure and test software service platform.
3. Activate platform and deploy ECM solutions across the enterprise.	7 months	• Visit each business unit office. • Assess individual business unit operational needs. • Build and deploy ECM service across 12 government program areas.

A plan of systematic interviews with these key executives formed the functional requirements for the project. Interviews served two purposes: They would surface the strategic and operational goals for their operations, and they would engage the active participation of the stakeholder to adopt the deployed system.

Using force field analysis,[3] the team engaged earlier adopters (drivers) and later adopters (restrainers). More specifically, the team initially focused on the IT executive stakeholders. As the team established successes throughout the project's progression, the team broadened the program to include additional business unit stakeholders. The team surveyed the entire agency with the aim of designing a universal, robust service platform.

The assessment provided interesting results. Even though business units varied, the practice of managing documents (assets) proved to be universal, and common themes of functionality emerged:

- Fast storage of documents.
- Easy and quick location of documents.
- The ability to co-author and collaborate on documents.
- The ability to share documents.
- Access control for documents.
- Document version control and the ability to revert to previous versions.
- Automatic retention of documents based on individualized schedules.
- Secure disposal and destruction of documents.
- Automatic alerting of document changes and access.
- Auditing of system access.
- Automatic routing of documents for approval processes.

In addition to business unit operational needs, the organization had external and internal requirements, needs and standards for enterprise applications. The project team researched the internal organizational process assets (government regulations, internal policies and internal procedures) and external best practices (*ISO/IEC 9126-1:2001—Software engineering—product quality*[4, 5]) to identify the nonfunctional requirements of the system. Again, a theme of key requirements emerged: information security, reliability, maintainability and performance. Figure 1 (p. 39) shows software quality characteristics according to ISO/IEC 9126.

The state of Ohio emphasized information security—protecting the privacy and confidentiality of client and employee information. Strong safeguards had to be established to:

- Classify data according to its sensitivity through a structured decision-making model.
- Identify the users of data and set permissions appropriately.
- Establish permission management procedures through which the owner of the data manages permissions.
- Secure data at rest.
- Secure data in motion (downloading, transferring and sharing).
- Track and monitor system to record and alert when data are accessed.
- Implement an annual audit to review information security operations and procedures.

Reliability of operations also is required. Business operations must be able to operate continuously and

Evaluation criteria / TABLE 2

Enterprise content management critical features
• Adequate capacity to store and process estimated operational needs.
• Permissions management.
• Version management.
• Recovery of documents and assets: backup and recovery.
• Records management (prevention from change and regulatory records retention).
• Auditability of access to assets.
• Support for file formats: American National Standards Institute text, binary (Word, Excel, Access, PowerPoint), PDF, graphics, audio and video.
• Support of concurrent users.
• Notification of document changes.
• Ease of inserting documents (usability).
• Ease of capability to share documents.
• Ease of locating assets (search).
• Automated routing of documents through predefined work stations.
Vendor and product critical success factors
• Quality (absence of defects and thus reliability).
• Performance (capability and scalability to provide support for estimated enterprise volume).
• Proven performance and past experience with the vendor and technology (risk reduction).
• Longevity (long-term survival of vendor and support).
• Maintainability (using component based approach without dependence on custom coding).

predictably within their service level agreements (SLA). Based on discussions with the stakeholders, the project team created a high-level SLA for the service platform. Fulfilling the reliability requirement was incorporated directly into the system design. Key quality and reliability features included:

- Using high-quality, durable hardware and software.
- Using skilled technical team members to build and configure solutions.
- Using database clusters that were redundant with fail-over capability.
- Using redundant application servers to provide uninterrupted service.
- Creating a separate disaster recovery service platform in a different geographic location with real-time data synchronization with the production system.

The need for high-quality, durable hardware and software returned the team to ISO/IEC 9126. Hardware, software and vendors needed to demonstrate capability, capacity and reliability—defect-free, robust, fault tolerant and able to recover from failures.

Technical competencies of project participants are often overlooked in project quality planning. Project results often vary significantly depending on the resources used. The project team explicitly aimed to secure the organization's best hardware, software, storage and network engineers to improve the probability of success for the project.

Maintainability and performance were valued critical components of project success. Learn more about how the team achieved enhanced maintainability and performance for the system by reading the online sidebar, "Maintainability and Performance," on this article's webpage at www.qualityprogress.com.

The completion of the first phase resulted in a planning and architectural document that was well-suited for the business's operational goals. This document, which guided the next phase, provided the high-level goals of the clients, high-level requirements, and architectural design of the system that would fulfill functional and nonfunctional needs. Up-front quality planning—the identification of the client needs, clarifying the acceptance criteria of the client and aligning to those criteria—provided a strong foundation for the project success.

Online Extra
View a video of William Minckler discussing more about enterprise content management systems at www.qualityprogress.com.

Phase two: building the ECM

Phase two consisted of selecting the support team, conducting design walkthroughs with the team, building and testing the platform and establishing production support.

The base project team recognized the importance of recruiting technical specialists that fully understand the various components of the platform. Much like engaging stakeholders, the project team secured the specialists early in the project to ensure that they would adopt and support the final system. Technical specialists who were involved in design reviews and construction were much more likely to claim accountability for the quality of the solution. Furthermore, involving expert skills dramatically reduced project and system risk. Technical specialists included in the project were:

- An enterprise architect/SharePoint architect.
- Microsoft server administrators.
- Database administrators.
- Storage specialists.
- Network specialists.
- Information security specialists.
- An application development specialist.

The expanded project team—the base team and cross-functional technical specialists—conducted repeated group walkthroughs of the design platform. Joint face-to-face team meetings significantly enhanced quality and reduced risks of the project. The technique of structured, interactive and collaborative peer review meetings offered:

- The most ideas.
- Discussion on the interaction of components.
- Clarification of roles and responsibilities.
- Identification of risks and opportunities for improvement.

Using a team approach offers significant advantages. The entire team engages in the accountability for the quality of the system. Also, when design defects are identified earlier, they are significantly easier and less costly to correct than after equipment has been purchased and installed. Learn more about the technical IT aspects of the final design by reading the online sidebar, "Design Details."

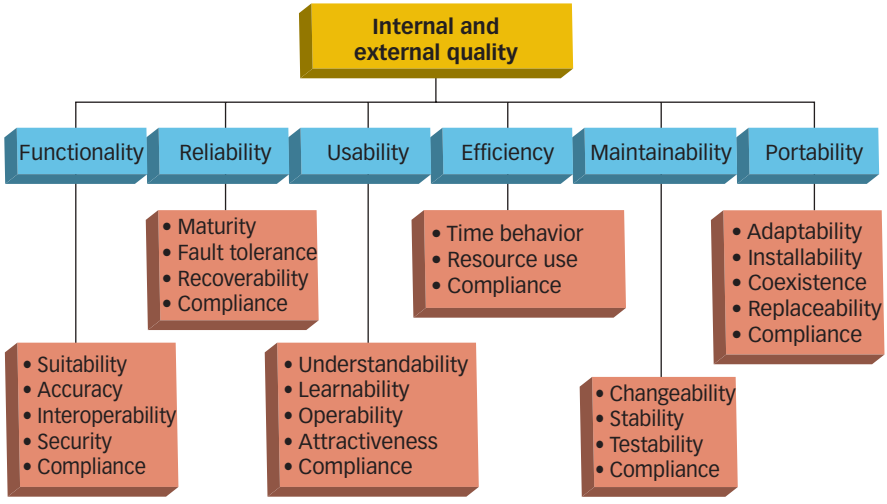
During the final build, continual testing was done at component and system levels. Individual system components (servers, databases, storage and networks) were tested. Following individual (unit) tests, the entire system was tested during integration tests. Volume

testing, load testing and stress testing were conducted to ensure the system would perform reliably when operating.

To complete the last step of the build process, the project team completed documentation and clarified roles and responsibilities. Documentation is often an overlooked yet key organizational asset. Instead of an "I'll get to that" approach, the team valued documentation as a tool for quality service delivery. Documentation serves the organization in:

- Incident management (resolving production problems in a timely manner).
- Audits (assessing compliance with information security and reliability requirements).
- Shared understanding (ensuring multiple members of teams can support applications).
- Avoiding waste (storing and transferring knowledge to avoid relearning and retraining).

Software quality checklist based on ISO/IEC 9126 / FIGURE 1



The project manager emphasized and negotiated a commitment from the support teams to identify and store proper production support documentation, such as key architectural documents, system parameter settings, passwords, key internal contact information and key external contact information to readily resolve technical problems. Emphasizing the quality requirement of reliability (per ISO/IEC 9126), the team ensured all key documentation was stored in a redundant, mirrored disaster recovery system to ensure continued service during catastrophic events.

Clarifying the roles and responsibilities of support team members and gaining resources and training on incident resolution procedures helped to ensure that problem resolution efforts were well coordinated and executed swiftly.

Phase three: activation and deployment

In the final phase, the project team embarked on using the SharePoint ECM platform to provide ECM functionality across the 12 offices of the agency. The newly built, centralized SharePoint ECM platform allowed each department to use the platform in a manner tailored to their business operations.

At a planning level, the project team canvassed the 12 offices of the agency. The project team formulated a plan that ranked in order the offices from early adopters to later adopters. The goal was to seek early successes and use those successes to drive change in subsequent offices. To order the deployment, the team engaged force field analysis and stakeholder analysis to gauge office readiness. Factors that affect the ability to adopt new technology include:

- Attitude of the individual office (adopting versus resisting change).
- The comfort level of the office with technology and technical operations.
- Value, return on investment or yield of potential operational changes.
- The role and importance that documents play in the operations of the office.
- Size of the document repositories and document operations.
- Existence of legacy systems and subsequent data migration efforts.
- Timing of office operations—avoiding heavy production periods.
- Availability of office resources to participate in planning, execution and training.

To achieve quality, consistent and predictable results, the project team created a consulting model that was repeated across the 12 offices. A pair of project

Quality does not come by accident; it must be **valued and overtly planned** into the product.

team members visited each office across the enterprise. The eight-step consulting model transported the client from goals evaluation to post-deployment follow-up:

1. Meet to identify and share an understanding of the client's goals.
2. Gather detailed requested functionality for each office.
3. Explain taxonomy and search techniques. Taxonomy refers to the controlled vocabulary (terms) used to tag, classify and manage documents.
4. Prototype a solution.
5. Iterate and gain client acceptance.
6. Create a plan to migrate legacy data into the SharePoint ECM.
7. Establish operational ground rules, policies and procedures to ensure the department uses the system consistently. Clients will more readily adopt a system they understand.
8. Monitor and follow up.

Measuring success was important for team feedback and reporting to senior management who invested in the initiative. With the goal of measuring the efficacy of the entire project, measurements covered operational, client satisfaction and quality information system metrics.[6] See the online sidebar "Measuring Project Success" to learn more about how project success was measured.

Quality = asset

Documents and records are key artifacts within an organization. They chronicle transactions, legal obligations, customer records, employee records, product designs and trade secrets. ECM systems bring tremendous power to managing these organizational assets. A full-featured ECM enhances the quality of storage, accuracy, retrieval and maintenance of these assets.

In this project, quality was recognized as an asset from its inception. Quality was inherently woven into each phase of the project: specifying product evaluation criteria, assessing the true needs of the client, referencing quality management standards in the design phase, comparing the built product to quality management standards, and using the plan-do-check-act approach to deploy solutions with follow-up procedures to measure customer satisfaction and the efficacy of results.

Quality does not come by accident; it must be valued and overtly planned into the product. External and internal quality management standards provide a valuable collection of critical success factors that should be consistently reviewed to ensure quality factors are addressed.

Quality is an asset—not a cost or afterthought. It ensures a product will meet the true customer needs. It is insurance for more business. QP

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Conducting FMEAs for Results

Tips and techniques for properly using the risk management tool

TODAY'S WORLD IS fraught with risk. A failure mode and effects analysis (FMEA) is a prevention-based, risk management tool that focuses the user or team on systematically:

- Identifying and anticipating potential failures.
- Identifying potential causes for the failures.
- Prioritizing failures.
- Taking action to reduce, mitigate or eliminate failures.

The real value of the FMEA is reflected in its use as a long-term, living document. It is essential that the document is owned and updated as changes are made to the design or the process.

FMEA was first developed and used by reliability engineers in the 1950s to study malfunctions of military systems. As such, it has been a worthy and valuable technique. Subsequently, it has become commonplace in just about every lean Six Sigma practitioner's tool kit. As common as the tool is, however, it is often used incorrectly. Users who invest significant time and effort in the tool often do not reap all it has to offer.

This column details FMEA and provides useful tips for gaining the most benefit from the use of this tool.

Types of FMEAs

The lean Six Sigma practitioner is likely to encounter two types of FMEAs:

1. **Design FMEA (DFMEA)**—an analysis process used to identify and evaluate the relative risk associated with a particular hardware design.
2. **Process FMEA (PFMEA)**—an analysis process used to identify and evaluate the relative risks associated with a particular process design.

Both are similar—with the exception of the first column of the FMEA document. Table 1 provides an example of an FMEA document's format.

The DFMEA's first column uses a product, assembly, subassembly or part. By contrast, the PFMEA uses a process. Therefore, the first column contains the process steps. As such, a process map, cause and effect matrix, suppliers, inputs, process, outputs and customers (SIPOC) diagram, value stream map, cause and effect diagram, or something similar, usually feed it.

The PFMEA document

Of the two primary types of FMEA documents, the lean Six Sigma practitioner likely will deal with the PFMEA the most. The PFMEA document's columns include:

1. Process step—Identify the process step and input under investigation. Each step is identified sequentially. If the PFMEA is fed from a cause and effect matrix, only high-value steps might be listed.

2. Potential failure mode—Identify all the ways a failure can occur at this process step.

3. Potential failure effects—Identify all the effects each failure mode has,

FMEA document general format / TABLE 1

May be a product, assembly, subassembly or part

Initial development of the FMEA | Improvement activities | Post-improvement activities

Process step/ input	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	Current controls	DET	RPN	Actions recommended	Resp.	Actions taken	SEV	OCC	DET	RPN
1	2	3	4	5	6	7	8	9	10	11	12	13			

DET = detection
FMEA = failure mode and effects analysis
OCC = occurence
Resp = responsible
RPN = risk priority number
SEV = severity

Many-to-many relationships between key columns / TABLE 2

Process step/input	Potential failure mode	Potential failure effects	Potential causes	Current controls
n	1	1	1	1
				2
				3
			2	4
				5
				6
		2	3	7
				8
				9
			4	10
				11
				12
	2	3	5	13
				14
				15
			6	16
				17
				18
		4	7	19
				20
				21
			8	22
				23
				24
	3	5	9	25
n + 1	4	6	10	26

Severity scale example / TABLE 3

Severity value	Descriptor	Description
1	None	No effect
3	Minimal	Greater than $1,000 and up to $100,000 in damages
7	Moderate	Greater than $100,000, but less than $1 million in damages
10	Extreme	Loss of life without warning or greater than $1 million in damages

Occurrence scale example / TABLE 4

Occurrence value	Descriptor	Description
1	Highly unlikely	1 in 10,000
3	Unlikely	1 in 1,000
7	Likely	1 in 100
10	Highly likely	1 in 10

Detection scale example / TABLE 5

Detection value	Descriptor	Description
1	Almost certain	$P(\text{detection}) \geq 0.95$
3	Likely	$0.50 \leq P(\text{detection}) < 0.95$
7	Possible	$0 < P(\text{detection}) < 0.50$
10	Not possible	$P(\text{detection}) = 0$

including the effects on the customer. Use a new line for each failure effect. Table 2 demonstrates the many-to-many relationships that exist across the document columns for any given step.

4. Severity—Quantify the severity of the impact of the failure effect. The scale for severity ranges from "no effect" on the low end to "safety hazard"—up to and including "loss of life without warning" on the high end. Also, the effect can be expressed in monetary damages, as well as destruction and delays. All scales must be described in the context of the FMEA situation. See Table 3.

5. Potential causes—Identify all root causes leading to the failure. If root causes are unknown at the time the FMEA is conducted, it may be necessary to divert from the FMEA temporarily and conduct a root cause analysis using the variety of quality tools available.

6. Occurrence—Quantify the frequency of occurrence of the failure mode. The scale for occurrence ranges from "highly unlikely" on the low end to "highly likely" on the high end. Some users, teams and organizations will go to great lengths to provide absolute definitions for the frequency of occurrence. For example, the Automotive Industry Action Group[1] stated that an occurrence entry value of one designates a possible failure rate ≤ 0.01 per thousand vehicles/items, and an entry value of 10 designates a possible failure rate ≥ 100 per thousand vehicles/items. The occurrence scale generally will translate to a rate or even a probability. See Table 4.

7. Current controls—Identify all the existing controls and procedures, including inspections and tests, which prevent the cause of the failure mode. Include a standard operating procedure number, if available.

8. Detection—Quantify the ability to detect the failure at a specific process step (that is, not at a previous or subsequent step, but at the step under consideration). The scale for detection ranges from

"almost certain" on the low end to "not possible" on the high end. See Table 5.

9. Risk priority number (RPN)—Determine the multiplicative effect (that is, RPN = severity value x occurrence value x detection value) of values assigned to columns four, six and eight, respectively. Although teams generally work the highest RPN values first, they may set additional prioritization criteria, such as working any line item on the FMEA where the severity value is at the highest level, the detection value is at its highest or any value is at its highest.

10. Actions recommended—Recommend actions for reducing the severity of the impact, frequency of occurrence or the ability to improve detection.

11. Responsible—Identify who is responsible for the actions recommended. If more than one individual is identified, a lead should be specified as responsible.

12. Actions taken—List the actions taken and completed, and include the completion date.

13. Severity, occurrence, detection and RPN—Identify new severity, occurrence and detection values, and compute the new RPN value. These have the same meaning as items four, six, eight and nine, respectively. However, these values reflect the actions taken in item 12. Ideally, one or more of these values will be reduced by the actions taken, resulting in a lower RPN value. If the value is not reduced, the actions taken were ineffective.

Developing the scales

For FMEAs to be successful, a team must seriously consider the scales it will use to assign values to each component of the RPN.

Some authors advocate using a 10-point scale. One issue with it is it tends to promote debate as to whether to assign an item a two versus a three, or a five versus a six. In such instances, the overall influence on the RPN value may be minimal, yet the team wastes significant time and energy debating values that are close together.

In contrast, other authors advocate using scales skewed and sparse in terms of assignable values. For example, instead of selecting a one-to-10 scale, some teams will choose one, three, seven and 10 scales, or something similar. The benefit of this type of scale is that it minimizes meaningless debate on close values and forces the team to discuss how to assign values.

Further, it bounds the RPN values between one and 1,000 (inclusive), which is convenient and easy to understand. Regardless of the scales used, they should be well defined, consistent and clearly understood by each team member.

Table 6 provides an example of a PFMEA for two failure modes for the first step of a process. Notice the severity and detection values are high in the first row. The detection control is ineffective, and the recommended actions attempt to address both of these issues. The recommended actions were taken, but only affected the detection value.

After applying revised values, the new RPN value is 10. This represents a significant drop from the previous RPN value of 300.

Although the severity value remains at a value of 10, the occurrence value dropped from a three to a one. Therefore, the team felt that because the failure is "highly unlikely" to occur, it will "almost certainly" be detected when it does. Consequently, the team decided not to pursue any additional improvements. Of course, this might be debatable.

In the second row, no current detection control mechanism exists. Therefore, the team must default to the highest value on the scale, which is a 10 in this case. This results in an RPN value of 490.

Thus, a simple action recommended is to separate the parts. This makes the revised

PFMEA example / TABLE 6

Process step/ input	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	Current controls	DET	RPN	Actions recommended	Resp.	Actions taken	SEV	OCC	DET	RPN
1	Part not installed	Device does not work	10	Process step skipped	3	SOP 123: process routing sheet	10	300	Modify program to halt production	T. Kubiak 06-17-14	Program modified to detect missing parts	10	1	1	10
1	Wrong part installed	Device overheats	7	Parts co-mingled in bin	7	None	10	490	Place different parts in different bins	T. Kubiak 06-17-14	Parts sorted and new bins added	7	1	3	21

DET = detection
OCC = occurence
PFMEA = process failure mode and effects analysis
Resp = responsible
RPN = risk priority number
SEV = severity
SOP = standard operating procedure

detection value a three and the resulting RPN value a 21.

Useful tips

More often than not, conducting an FMEA work session can be time consuming, tiresome for all and, in many cases, less than productive. Here are tips to make the sessions more meaningful:

1. Establish team norms.
2. Keep sessions to a reasonable length of time.
3. Establish an FMEA owner.
4. Use subject matter experts.
5. Use a professional facilitator.
6. Create meaningful scales.
7. Set up a trigger to start an FMEA update.
8. Limit the ability of participants to review past decisions for current steps.
9. Remember all decisions reflect the current step.
10. Write modes, effects, controls and causes in clear and meaningful ways.
11. Complete each step in a given work session to the extent possible.
12. Minimize the duration between sessions.
13. Identify root causes.
14. Score appropriately.
15. Support FMEAs with additional quality tools.[2]

These tips are explained further in the online version of this column at 3.4 per Million's webpage at www.qualityprogess.com.

Up-front work

FMEAs should be owned, considered living documents and updated appropriately. They require intensive work up front on the part of the team, but their value is almost immeasurable in terms of providing a positive impact on quality. The tips provided are borne from experience and, if applied, will ensure the effectiveness of your FMEA. QP

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Saying Goodbye to Dad

Family uses quality method to make difficult end-of-life decision

MY DAD'S health was on the decline for many years. But last spring, his heart's condition deteriorated rapidly after a fall. At first, he just needed some help balancing as he walked around the house. Within a week, he needed help getting into and out of bed. By the following week, he could barely get up on his own. Because my Mom was the only one home with him, the burden of lifting and moving a grown man was devastating to her back problems. Plus, there was the possibility she'd drop him.

My two brothers and I went back home to help Dad and provide input on his care options. At first, a nurse's aide came to the house. We also considered hospice care, but Dad was not ready to give up (a requirement of hospice care).

As we explored our options, differing opinions of family members created friction. My older brother, who had watched his father-in-law die of cancer in the hospital, emphatically felt that Dad should spend his last days at home among familiar surroundings. Mom, who had the ongoing burden of caregiving, wanted him in a place where he could be tended to by professionals strong enough and able-bodied enough to do the job. My younger brother and I had mixed emotions, but primarily we wanted whatever would extend Dad's life. Dad wanted whatever was best for Mom. Our biggest wish—for Dad to live forever—was unfortunately not an option.

As a former college professor and consultant who teaches the analytic hierarchy process (AHP), I suggested AHP to help us evaluate the choices and agree on the best solution. In short, AHP is a method to derive ratio scales from paired comparisons. It took less than five minutes to explain that instead of trying to directly select the best care option, we should identify and prioritize the criteria we use to determine "best."

We brainstormed ideas, structured them into a hierarchy, gave our opinions and voted pair-wise, taking the geometric average of our votes when we could not reach consensus. Criteria (and weights) included, "easy on Mom" (0.256), "Dad is free from pain" (0.409), "can interact with family and friends" (0.196) and others.

Pairing took some time to complete because of the emotions involved. We were frequently interrupted by visitors and phone calls from well-wishers. AHP allowed us to pick up exactly where we left off without rehashing agreed-upon decisions. We didn't argue with one another because we did not have to reach consensus and could individually vote based on our opinions.

Averaged results were entered in the AHP matrix. Using natural language (such as moderately or extremely) instead of numbers helped keep this on a human level rather than become a mathematical exercise. We could even address judgment inconsistency ($a > b$, $b > c$, $c > a$). Our inconsistency ratio was 0.08, an acceptable level.

Coping as a family

After the decision criteria were prioritized, we reviewed the healthcare options: nurse or nurse's aide in the home, hospice in home, nursing home, hospital, hospice and hospital in the hospice, a new but seldom mentioned option. Based on brochures, websites, interviews and our experiences during the previous weeks, we evaluated each option in terms of how it met the decision criteria.

Institutional options were highly rated in terms of "easy on Mom," and "Dad is free from pain." Home options were highly rated for "can interact with family and friends" and "comfortable surroundings."

We spent less than two hours on the AHP model. The AHP model prioritized options by synthesizing the best care choice based on the prioritized criteria. The leading option was hospital in the hospice with a priority of 0.283 and an acceptable inconsistency ratio of 0.07.

Dad was admitted to the hospital in the hospice, and we spent the last few days of his life emotionally enjoying one another instead of running around and taking care of his physical needs. Dad died in his hospice bed with Mom and I at his bedside. He was lucid until the day before he finally exhaled and never inhaled.

Later, Mom raved to their rabbi about how I helped the family through this difficult time. He was astounded because decision making can cause incredible friction within grieving families. Decisions often take days or weeks and can alienate some family members.

The AHP process gave my family strength and solidarity to stand up to the healthcare system, which often gave us disparate and conflicting advice. We presented one face and one decision that we expected to be honored. QP

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The ASQ Global State of Quality

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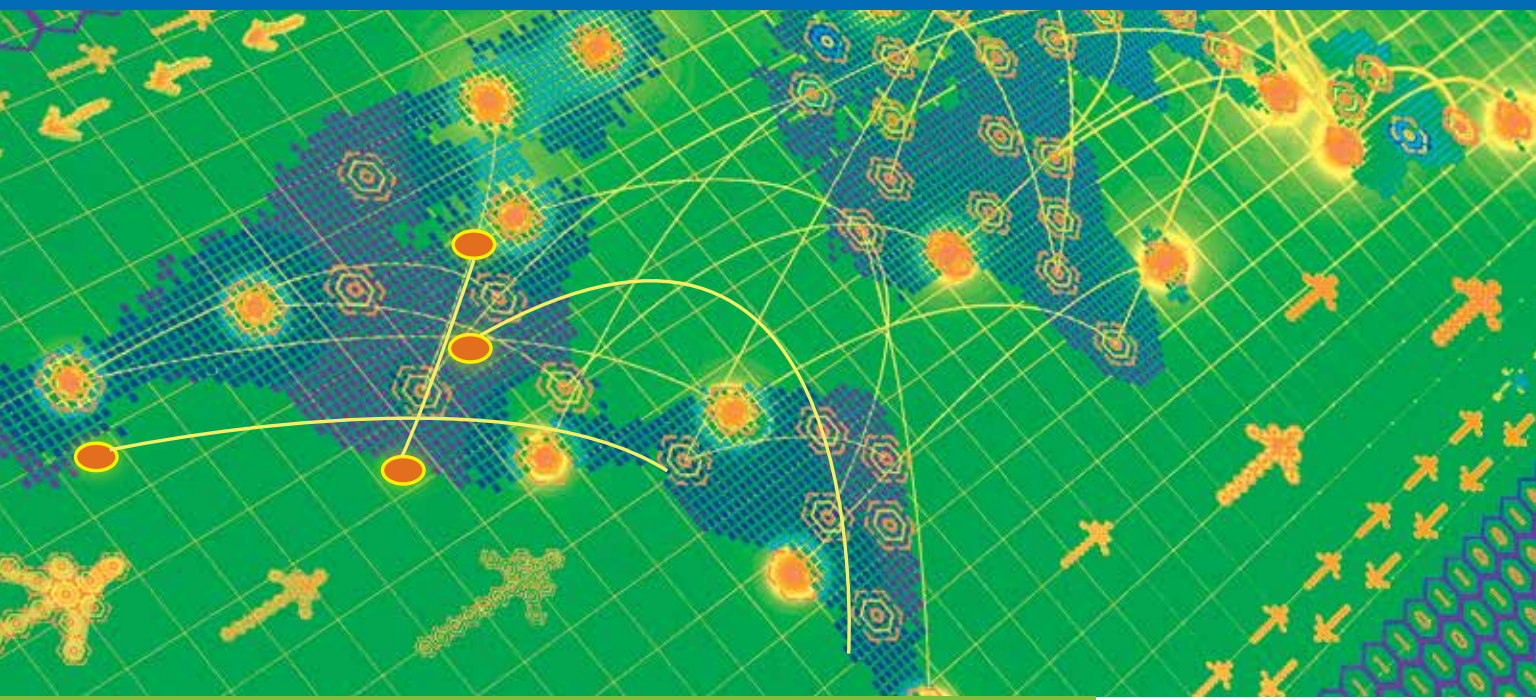

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Survival Instincts

Eat or be eaten in today's job market

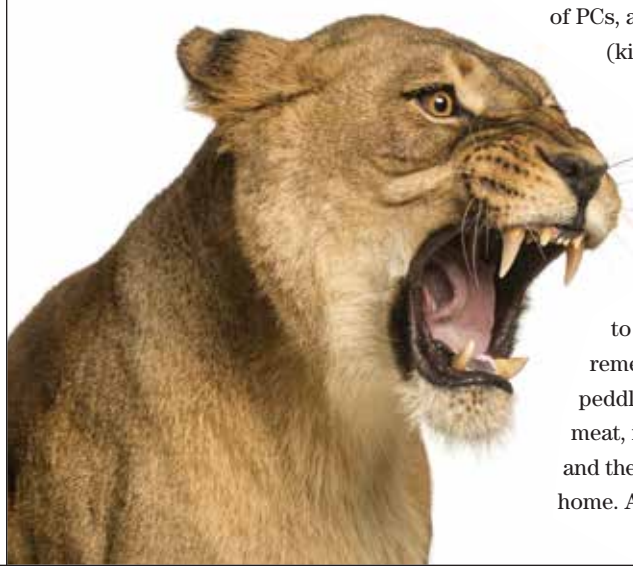
"Every morning in Africa, a gazelle wakes up knowing it must run faster than the fastest lion or be killed. Every morning, a lion awakens knowing it must outrun the slowest gazelle or starve to death. It doesn't matter if you are a lion or a gazelle—when the sun comes up you'd better be running."[1]

AN OMINOUS OPENING, I admit, but doesn't this passage ring true in the world we live in? For individuals and organizations, the hard-knock economy takes its toll on basic survival. Even as unemployment claims slowly decline, we hear about the thousands who gave up looking for a job.

Because of the long-lasting economic crunch, employers have learned how to survive with fewer people on the payroll. Rapid technology advances have lessened the need for lower-level, nontechnical positions and increased the need for highly trained and skilled workers. We hear of critical shortages of qualified employees, while thousands of former workers remain unemployed for not having the required skills, knowledge and certifications. These are symptoms of a changed professional landscape. While there are several possible root causes of unemployment, one of the easiest to remedy involves updating individual knowledge, skills and experience. Are you running yet or are you still asleep?

I am continually amazed and disturbed that a number of my friends and colleagues do nothing to sharpen their skills or enrich their knowledge. Continuous learning is a must in today's professional jungle. Complacency and procrastination are your deadly enemies. Watching TV for hours each day does provide a drizzle of useful information, but it is a poor substitute for studying or learning something new and useful. Although I earnestly work at learning something new each day, I admit that the rapidly changing technology used to gather, access and store information presents ongoing challenges for me.

I grew up in the ancient world of punch-card tabulation and progressed into the mainframe computer realm. I stumbled my way into the chaotic domain of PCs, and now I am being pulled (kicking and screaming) into the exploding maze of hold-it-in-your-hand and store-it-all-in-a-cloud era of IT.



As I sputter and fume about my computer's relentless pursuit to drive me crazy, I can still remember horse-drawn wagons peddling milk, bread, produce, meat, ice and knife sharpening, and their welcome arrival to my home. Although I'm in a business of facilitating change, I confess that I exhibit some resistance to substantially altering my familiar lifestyle.

Recently, my local supermarket implemented an option to buy groceries online and pick them up at a station outside or have them delivered. It's unclear whether customers will buy more or less using this new service. Self-checkout counters have been in place for a number of years and have replaced friendly and helpful people to a degree. Now, only one employee is needed to assist and instruct the occasional technology-challenged buyer. Computerized checkout confuses some customers and forces others to wait in long lines at the remaining full-service counters operated by cashiers.

In 1966, *Time* declared: "Remote shopping, while entirely feasible, will flop."[2] Well then, allow me to get back in line where a friendly human will greet me with a smile. The self-checkout lines sometimes appear more jammed than lines for cashier service. As I write this, I realize that a learning opportunity is passing me by. I probably should learn how to use self-checkout before all the staffed counters disappear.

A friend of mine spent much of his work life in the auto repair industry until a few years ago. He bounced around the industry as auto dealers downsized or evaporated until he was eventually laid off as a parts-room supervisor. Finding a job in the same field was unrealistic. But he needed a solution quickly because he provided food and a home for a family of four and his savings were dwindling.

Instead of being drawn into a quagmire of debt and despair, my friend explored another option: What would it take to

Complacency and procrastination **are your deadliest enemies.**

obtain a position in the expanding field of healthcare? He learned he would need schooling to pass an exam and become licensed in the discipline he selected. Six months later, and less than two weeks before receiving his credentials, he landed a job at a prestigious healthcare center in town just three miles from his home. His enthusiasm and many talents enriched his initial job, and he was recently promoted. Although he's not making the same salary he earned while working for dealerships, he's happily on his way to better times and higher pay.

The 21st century translation of the adage that "time marches on" should be "time streaks onward." Where are you in the great game of life? More importantly, what are you doing about it? Are you striving to be ahead of the pack, or are you trailing behind? Read the passage under the headline again. Commit to continual learning for self-betterment. You'll never guess how much fun it can be until you do it. It's often much better than what you remember from your early days in school, and it beats TV. If you're unemployed or might be, learn something new and useful instead of merely waiting for the phone to ring. Wake up and start running. QP

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BY ALEXA DIBENEDETTO, ROGER W. HOERL AND RONALD D. SNEE

Solving Jigsaw Puzzles

Addressing large, complex and unstructured problems

WE ALL FACE problems in business, as well as in our personal lives and relationships. Despite the universal need for effective ways to address problems, there is surprisingly little agreement in quality or scientific literature on approaching problems in general.

Problem-solving frameworks tend to be designed for narrow, well-defined problems. Unfortunately, the most significant problems faced by modern society tend to be large, complex and unstructured. In other words, they're not well defined. How should we approach these types of problems?

Previously, the use of statistical engineering was suggested as a way to address such large, complex and unstructured problems.[1-3] Roger W. Hoerl and Ronald D. Snee defined statistical engineering as "the study of how to best use statistical concepts, methods and tools, and integrate them with IT and other relevant sciences, to generate improved results."[4]

This article focuses on what can be learned from diverse disciplines on addressing large, complex and unstructured problems. We therefore provide a broader context—coming from diverse disciplines—in which to view statistical engineering. In general, this broader viewpoint reinforced several observations by Hoerl and Snee, and also led to some unique insights.

How do other disciplines do it?

Virtually every discipline faces large, complex and unstructured problems. To obtain a sampling of this diversity, academics in math, psychology, engineering, economics and biology were interviewed, and numerous publications from these and other disciplines were reviewed. For the sake of brevity, only a few highlights from this research are noted.[5]

The problem-solving process in psychology typically focuses on brain activity and the personality traits that contribute to the way we solve problems. For example, Sascha Topolinski and Rolf Reber define and interpret the "a-ha moment"—that sudden moment of clarity in which a person realizes the answer to the problem he or she has been trying to solve.[6] The four key components of the a-ha experience are suddenness, ease, positive affect and the feeling of being right.[7]

In a popular problem-solving manual, Graham Wilson describes the way personalities affect decision-making styles.[8] He suggests that your preferences inherently affect the way you make decisions, which implies that sound problem-solving invariably involves diverse teams with different personalities. In terms of personality, a concern raised by economics professor Lewis Davis is that creativity cannot be effectively taught, but it is often what separates successful and unsuccessful problem solvers.[9]

A related consideration is who should be making the decisions. One pitfall to avoid during group decision making is a phenomenon called groupthink in which members "let their need to agree with each other interfere with their ability to think about the decision critically."[10]

According to psychology professor Erika Wells, one of the important aspects of problem solving is the size of the problem space.[11] The larger the problem space, the longer it takes for us to acknowledge all of our variables and alternative approaches and test them. Thus, we should always take steps to try to reduce our problem space as much as we can, which usually

involves a subject matter expert.

An interesting twist on team problem solving and personalities comes from engineering in that a unique difference between engineering and other fields is the explicit emphasis on teamwork.[12] Most engineering problems require a significant amount of background knowledge in a variety of fields, which would be unreasonable for any one person to know. Therefore, combining effort from team members with unique expertise allows teams to develop creative and effective solutions. Of course, most disciplines require teamwork to be effective; according to mechanical engineering professor Brad Bruno, this need is just more explicitly emphasized in engineering.

In the context of big data analytics, Olaf Wolkenhauer and his co-authors note the need to have an interdisciplinary approach to solving large and complex problems in biomedicine: "Many scientific questions require a range of expertise from different fields. Therefore, integration across disciplinary boundaries is crucial. The expertise for particular technologies and experimental systems is rarely found in a single laboratory, institute or country, and this raises the need for standards and ontologies that support the sharing and integration of data and models."[13]

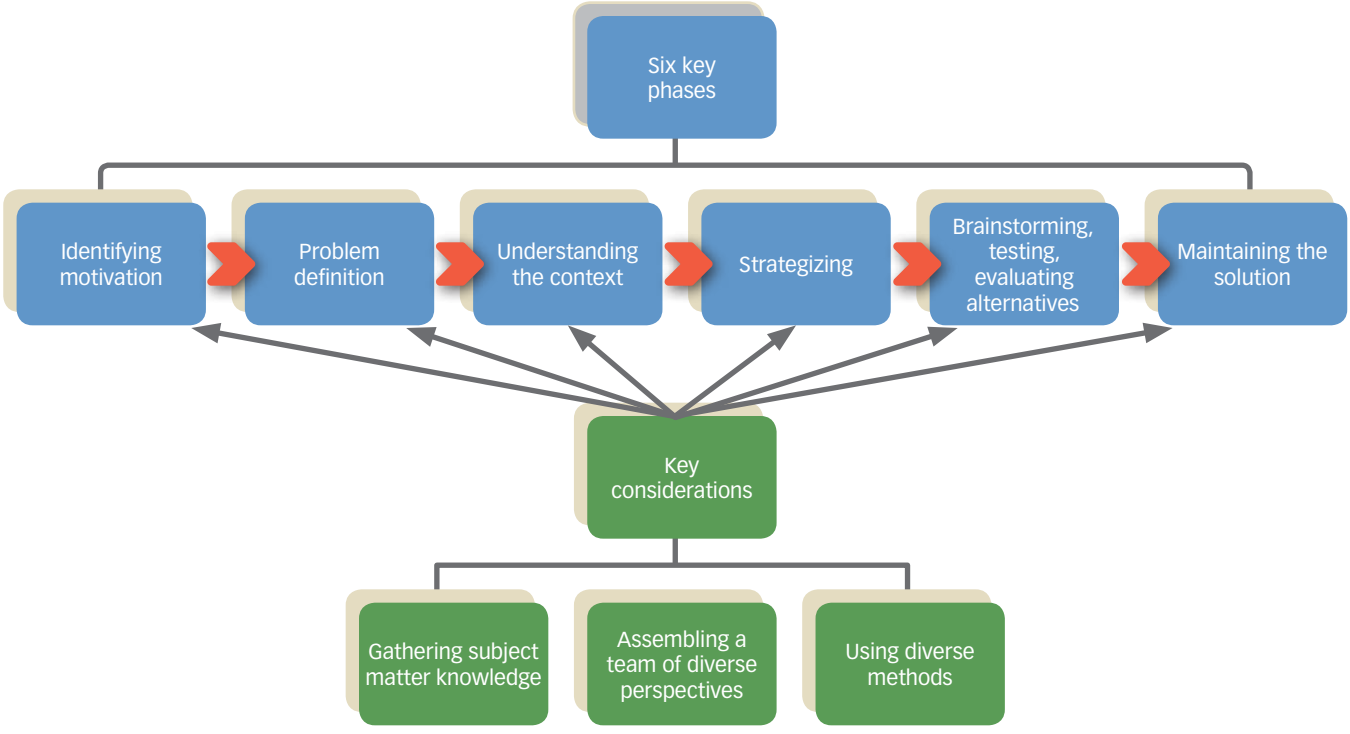
It is generally understood that solving complex problems requires some type of strategy or multi-step process. For example, Wilson suggests five steps to solve emergency problems: identify the problem, explore alternatives, select an alternative, implement the solution and evaluate the solution. Wilson notes that problem identification is often the most important and most difficult step in the decision-making process.[14]

Wilson emphasizes the importance of consciously considering all of these steps, while it may not always be necessary to write down or formally document all. Wilson breaks down each step into smaller pieces to make it clearer and easier to understand. This produces specific tactics within the overall strategy.[15]

Andreas Fischer and co-authors discuss another multi-step method called complex problem solving and explain how it applies to various fields.[16] They highlight five key points of this process: information generation, information reduction, model building, dynamic decision making and evaluation. These authors further note that one of the most important aspects of problem solving in any field is to have knowledge of the tools needed to actually solve the problem (that is, applying equations and models), and subject matter knowledge (or an expert nearby).

TRIZ, also commonly referred to as the "theory of inventive problem solving" or "TIPS," provides an alternative problem-solving method.[17] The basis of this method

Key problem-solving phases and considerations from review / FIGURE 1



is that we can use already-established principles and insights from other fields that may not necessarily be related to what we're studying. If they are similar enough, we can apply these techniques from other disciplines to solve our new problems.

TRIZ is often used where we have to somehow avoid an inherent conflict within our problem, such as creating a high-powered aircraft engine that is also light. These two qualifications seemingly contradict each other: The most high-powered engine we could make is probably large and heavy, while the lightest engine we could make is probably not high powered.

What have we learned?

There are several recurring themes that appear throughout literature on large, complex and unstructured problems. DiBenedetto organized them into two macro themes—the first being a set of six key phases that, regardless of the problem-solving method used, a researcher must pass through and consciously consider.[18] While not a formal process in themselves, these phases cannot be skipped and must be considered regardless of the type of problem.

The second macro theme contains critical considerations for problem solvers during all phases of the problem-solving process. These conclusions, shown in Figure 1 (p. 51) and Table 1, support those of Snee and Hoerl, who stress that statistical engineering applications require logical phases and there is an underlying theory of key principles for statistical engineering approaches, regardless of which specific problem-solving method is used.[19]

As shown in Figure 1, the six phases required are (in order):

1. Identifying the motivation for solving the problem.
2. Defining the problem.
3. Understanding the context.
4. Strategizing.
5. Brainstorming, testing and evaluating alternatives.
6. Maintaining the solution.

Within the second macro theme of crucial problem-solving considerations, the critical principles are: gathering subject-matter knowledge, assembling a team of diverse perspectives and using diverse methods. These principles are not unique to any of the phases but are important in each.

Advice for problem solvers

We can make recommendations for problem solvers beyond the points listed in Figure 1 (see Table 1). First is that the phases and critical considerations are not meant as a "cookbook" to be followed in "seven easy steps," or as the best or only way of solving a complex problem. They are meant, however, to provide structure and some underlying theory for people who don't know how to attack a large, complex and unstructured problem.

One issue within the quality and problem-solving literature is that it spends too much time defending preferred methods and arguing as to which techniques are best. This is misguided effort because no single method can solve every problem.

The second recommendation for those responsible for addressing big problems is to spend a significant amount of time gathering the right group of people to assist them during the problem-solving process. This step is often overlooked because natural teams can form through existing relationships and problem-solving teams of the past. Each problem should be considered individually, however, so that various personalities and experts can be assembled to form a diverse, cohesive and productive problem-solving team.

Similarly, effective problem solvers must be comfortable using tools and techniques that they were not previously familiar with. It is easy to rely on the tools that you know have worked in the past, but when dealing with large, complex and unstructured problems, it is important to look outside of your traditional toolbox to produce novel solutions.

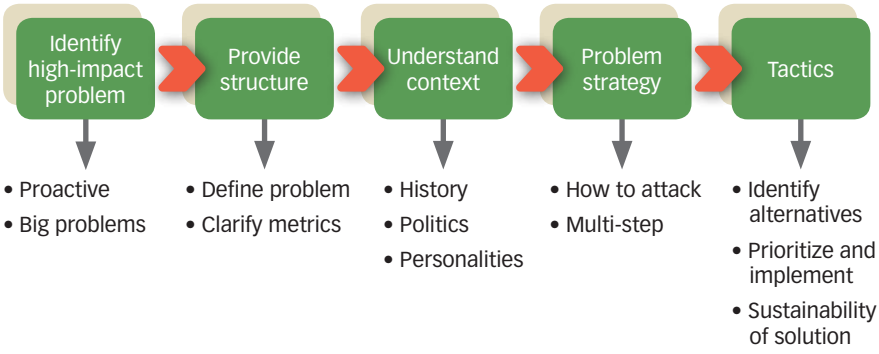
The next recommendation is to read Wilson.[20] This manual is intended to help people teach themselves problem-solving methods within the context of emergency situations. It may not seem relevant to the process of solving large, complex and unstructured problems, but it breaks down the process into its most basic definitions (that is, what do we define as a problem?), and provides various steps and methods for working through the problem-solving process.

The fourth recommendation is to give yourself more time than you think you might need to solve complex problems.

Recommendations for problem solvers / TABLE 1

1. Figures 1 and 2 show the phases of problem solving and are not meant as cookbooks, or suggested as the best or only ways of problem solving.
2. Project team selection is critical. Make sure that you have the right skills involved.
3. Become familiar with Graham Wilson's manual; it contains much useful advice.
4. Give careful consideration to project planning. Problem definition and solution identification, and data collection and preparation can be time consuming.
5. Make sure that the solution can be successfully implemented and sustained over time.

Phases of statistical engineering projects / FIGURE 2



Problem solvers should take the time to carefully define the problem, as this is the "make or break" aspect of the problem-solving process. Additionally, researchers and problem solvers could benefit from having time to create alternatives and analyze them, and have more time to contemplate these solutions and reflect on what they have accomplished. While modern society tends to schedule breakthroughs, solutions to large, complex and unstructured problems often take time.

A final recommendation is to make sure that after you have a solution, you can successfully implement and sustain the results. Our efforts would be futile if we spent our resources on solving a problem and could not implement and sustain the results. This implies that throughout the problem-solving process, including deciding which problems to work on, we consciously consider the long-term view of sustainability.

Statistical engineering

The results and recommendations discussed reinforce many of the conclusions of Hoerl and Snee. In particular, if you compare Figure 1 with previous models that Snee and Hoerl have proposed for the phases of statistical engineering projects,[21-22] you see a great deal of consistency. Therefore, we propose Figure 2 as integration of these previous models that hopefully combines the advantages of both. In particular, consider the last two phases of Figure 1 to be specific examples of the tactics you would employ in the final phase of Figure 2.

As this article shows, there are many problem-solving techniques used within various disciplines. The goal is to condense the literature on these methods to identify important themes that could help people solve big problems across disciplines. Collectively, we have attempted to integrate the key learnings of this external review into the previous work of Hoerl and Snee on statistical engineering. By using the guidelines and consciously considering the key themes proposed, you will have the framework necessary to successfully address large, complex and unstructured problems. QP

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Company Contact Information	AUDITING	BALDRIGE AWARD	BENCHMARKING	CALIBRATION	CAPABILITY STUDIES	COMPUTERS	CONSULTING	CORRECTIVE ACTION	CUSTOMER SERVICE	CUSTOMIZED SOFTWARE DEVELOPMENT	DATA ACQUISITION	DESIGN OF EXPERIMENTS	DOCUMENT MANAGEMENT	E-COMMERCE	GAGE REPEATABILITY AND REPRODUCIBILITY	INSPECTION	ISO 9000	ISO 14000	MANAGEMENT	MEASUREMENT	PREVENTIVE ACTION	PROBLEM SOLVING	PROCESS DOCUMENTATION/MAPPING	QS-9000/TS 16949	QUALITY ASSURANCE	QUALITY FUNCTION DEPLOYMENT	RECALL MANAGEMENT	RELIABILITY	SIMULATION	SIX SIGMA	SOFTWARE	STATISTICAL METHODS	STATISTICAL PROCESS CONTROL	SUPPLIER QUALITY ASSURANCE	TAGUCHI TECHNIQUES	TEST PREPARATION	TRAINING	OTHER
StatSoft 2300 East 14th Street Tulsa, OK 74104 Phone: 918-749-1119 www.statsoft.com STATISTICA StatSoft's STATISTICA (now part of Dell) integrates advanced analytics solutions with your data repositories for quality improvement, process monitoring, root cause analysis and sophisticated graphical reporting.	X			X		X	X		X		X	X		X				X	X	X	X			X			X	X	X	X	X	X	X	X	X	X
Sunday Business Systems 1160 Creekwood Drive San Jose, CA 95129 Phone: 408-217-9680 www.sundaybizsys.com Sunday Business Systems Sunday Business Systems provides cost-effective software solutions to achieve compliance to quality standards such as ISO 9001, AS9100, TS16949 and ISO 13485.	X			X			X	X		X			X	X		X					X	X		X			X			X	X	X	X	X			
Title21 Software 7031 Koll Center Parkway, Suite 110 Pleasanton, CA 94566 Phone: 925-484-2121 www.title21software.com Title21 software Title21 Health Solutions provides integrated electronic solutions that automate and streamline the critical processes of healthcare and life science organizations—delivering operational efficiency, reducing cost and improving quality.	X			X				X	X			X				X		X		X		X		X		X					X				X	X	X
VERSE Solutions 399 Conklin Street, Suite 208 Farmingdale, NY 11735 Phone: 423-388-3777 www.versesolutions.com verse solutions VERSE is a dedicated cloud-based quality management system that provides the dynamic performance of an on-premise solution without the long-term commitment.	X							X					X				X		X		X		X		X	X					X						X	X

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Bob Pence is CEO of Freese and Nichols Inc., a multiservice engineering, architecture, and environmental science firm with 15 offices in Texas and North Carolina. Pence led Freese and Nichols through the recession by supporting and enlarging the company's continuous improvement program, commitments to clients and employees, and corporate plan.

ALICIA BOLER-DAVIS

Alicia Boler-Davis is senior vice president, global quality and global customer experience at General Motors (GM) Co. This job expands her customer experience role from a U.S.-focused position to a global one. Boler-Davis reports to GM chairman and CEO Dan Akerson and is a member of the GM Executive Operations Committee.

SIMON T. BAILEY

Simon T. Bailey is a leadership expert who provides tips, tools and techniques on how to release potential in the world's most important asset—people. He is the former leader of the world-renowned Disney Institute and founder of Brilliance Institute Inc. *Meetings and Conventions* magazine called him as "one of the best keynote speakers ever heard."

Watch these sessions on demand at
http://videos.asq.org/on-demand-video-library.

QP TOOLBOX

Tabletop inspection system ▼

UniWest has developed a tabletop, three-axis, semi-automatic eddy current testing inspection system. The ES-1000 provides eddy current testing for rotationally symmetric parts, such as engine disk bores and webs.

For large organizations, including aircraft manufacturers and global aircraft maintenance facilities, the ES-1000's design allows sharing of existing components, such as probes, part-mounts and signal-processing instruments, as well as

computers and monitors, between eddy current testing systems. For regional facilities servicing smaller jet aircraft, the ES-1000's acquisition cost makes investing in a semi-automated eddy current system viable when compared to a full-scale system.

The modular ES-1000 system comprises four operationally independent components: turntable and gantry module; eddy current generation and processing instrument; eddy current probe; and computer and display, running Windows 7 or higher.

- Visit: www.uniwest.com.
- Call: 509-544-0720.

Distance sensor ►

Sick has announced the OD Mini short-range distance sensor for precise measurement tasks. Depending on the application, the OD Mini offers measuring ranges from 100 to 250 mm.

The OD Mini is a stand-alone device that uses a teach-in LED display or an external teaching input. The sensor is available in two sensor housings, including rugged 70-gram stainless steel housing for harsh environments and a lightweight 40-gram aluminum housing for standard applications.

The OD Mini is ideal for positioning, classification and quality control applications in the robotics, machine tools, electronics, automotive and packaging industries.

- Visit: www.sickusa.com.
- Call: 952-829-4728.

Smart aqua meter ►

The SAM-1 smart aqua meter from Sensorex measures and records pH, oxidation-reduction potential, conductivity and temperature values, and is compatible with Apple and Android smartphones and tablets. It delivers analytical measurements in the lab or field for use in environmental, education and industrial applications.

The SAM-1 plugs into the headphone jack of a smartphone or tablet and connects to Sensorex smart analytical sensors for measurement. The SAM-1 app is available as a free download, and recognizes the smart sensor type and calibration data.

Time, date and GPS location are recorded with each reading, and users may add location name and additional comments. Readings can be shared through email or exported to a spreadsheet for analysis and record retention.

- Visit: www.sensorex.com.
- Email: sales@sensorex.com.

Calibrators ▼

Fluke has released two single function calibrators for simulating process temperature sensors. The 712B and 714B thermocouple temperature calibrators allow instrument, process and plant maintenance technicians to test process temperature instrumentation.

The Fluke 712B measures and simulates 13 different resistance temperature detectors types and resistance. The 714B measures and simulates 17 different thermocouple types, as well as millivolts, to verify process sensors by direct comparison of measured versus reported temperatures. The calibrators also measure four to 20 mA signals with 0.001 mA resolution while simultaneously sourcing a temperature signal—with readings displayed on the backlit display.

- Visit: www.fluke.com.
- Call: 800-443-5853.

Encoder system ►

Renishaw's Atom noncontact optical linear and rotary incremental encoder system filters optics with auto-gain control and auto-offset control for signal stability and dirt immunity. Applications include laser scanning, precision micro stages, semiconductor, medical, microscopy, scientific research and space-critical motion control, inspection and metrology.

Atom offers analog speeds to 20 m/s and digital resolutions to 1 nm when used with Renishaw interpolation electronics. Scale options include linear and rotary scales in stainless steel and glass. A variety of high-accuracy scales is available, including industry-standard stainless steel tapes, high-accuracy linear glass spars and rotary glass discs from 17 mm to 108 mm in diameter.

- Visit: www.renishaw.com.
- Call: 847-286-9953.

Rotary encoders ▲

Heidenhain is offering the ERO 1200/1400 series of modular optical rotary encoders without integral bearing. The ERO 1200/1400 encoders are a noncontact solution well-suited for motion control use on dynamic stages and machines in the general automation or semiconductor industries, such as a pick-and-place machines. They also are used on air bearing spindles, blood pumps and servo motors in robotic applications.

With through-shaft diameters of 4, 6, or 8 mm, and a self-centering slide mechanism, the ERO 1400 is a small, versatile encoder with onboard interpolation and easy mounting. The ERO 1200 is available with a 10 mm or 12 mm shaft, offering a graduation accuracy of ±6 arc seconds.

- Visit: www.heidenhain.us.
- Call: 847-490-1191.

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QP REVIEWS

The Certified Manager of Quality/Organizational Excellence Handbook

Russell T. Westcott, ed., ASQ Quality Press, 2013, 688 pp., $99 member, $139 list (fourth edition, book).

Managers of quality and organizational excellence face a wide range of challenges on a daily basis in their attempt to reach and exceed organizational objectives. This handbook is a valuable resource that could help these individuals manage these challenges.

This book is organized into 20 chapters. Each chapter—except the last one, which includes a copy of the 2013 body of knowledge (BoK)—covers one or more unique topics and several BoK requirements associated with excellent quality management practices.

These requirements span the particular range of content and level that apply to preparing similar questions to those used in the ASQ certified manager of quality/organizational excellence (CMQ/OE) exam. Some of the book's topics include:

- Historical perspectives relating to the evolution of particular aspects of quality management.
- Key principles, concepts and terminology relevant in providing quality leadership.
- Benefits associated with the application of key concepts and quality management principles.
- Best practices describing recognized approaches for quality management.
- Guidance and prep for the CMQ/OE exam.

The authors could have more clearly identified the revised theories and applications by providing a summary of changes addressing the current global perspectives since its previous editions. In addition, I expected to see more references to the Project Management Institute BoK.

Regardless of these minor shortcomings, this book helps readers to prepare for the ASQ CMQ/OE exam in addition to providing information that can be valuable to managers who wish to improve business results in their organizations.

Herzl Marouni
Houston

The Certified Quality Inspector Handbook

H. Fred Walker, Ahmad K. Elshennawy, Bhisham C. Gupta and Mary McShane-Vaughn, ASQ Quality Press, 2012, 480 pp., $89 member, $135 list (second edition, book and CD-ROM).

This book is a good gauge to determine the range of topics you need familiarity with in order to pass ASQ's certified quality inspector (CQI) exam. The first part of the book is dedicated to the basic math used to measure, analyze, interpret and report inspections that would be performed by a CQI.

Then the book describes the inspection instruments and their functions. It also includes calibration and measurement system analysis activities, which help an inspector understand when to consider their results valid or not.

The book covers general inspection and test processes that guide the inspector on the shop floor. It helps the inspector determine appropriate sampling plans, and what to do if they find conforming or nonconforming material.

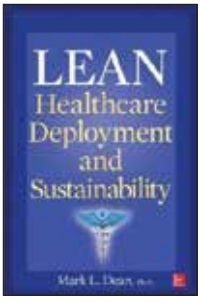
The second half of the book covers the basics of quality management system activities that inspectors can positively influence. The implication is that, with further in-depth training and experience, the CQI would be ready to become a certified quality technician.

A CD-ROM with sample test questions and answers comes with the book, and there are lengthy bibliographies at the end of each section to help CQI candidates prepare for the exam or find further information to help them with an issue on the floor.

Jeff Stevens
East Greenwich, RI

Lean Healthcare Deployment and Sustainability

Mark L. Dean, McGraw-Hill Professional, 2013, 240 pp., $30 (book).



This book provides a comprehensive overview of the steps involved in implementing lean methods in a healthcare setting, such as a hospital, clinic or long-term care facility. The book begins with a chapter on the lean process and the leadership required for implementation. A list of healthcare establishments that have successfully implemented lean is provided.

The author argues that because patients are living and perceiving human beings, it is essential to consider their satisfaction during their transition through the value stream or healing pathways. Critical steps

mentioned are: enterprise transformation, healing pathway transformation and process transformation. Each is discussed in great detail in subsequent chapters.

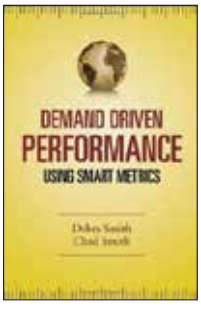
There are individual chapters devoted to planning and conducting the lean transformation summit, which focus on translating ideas into actions. There is a chapter on documenting the process for the future benefit of the organization.

This book explains how to implement lean in a healthcare setting in a detailed manner, and also presents a road map of the processes and tools required. It is a must-read for leaders and managers in healthcare settings that have been charged with the responsibility for leading lean initiatives.

Rangarajan Parthasarathy
Harvard, IL

Demand Driven Performance Using Smart Metrics

Debra Smith and Chad Smith, McGraw-Hill Professional, 2013, 336 pp., $70 (book).



Since 1997, the authors were specialist in the implementations and application of the theory of constraints, where they had great success. In 2003, they entered the software field and designed two software applications. One was used to schedule resources and manage the shop floor and the other to execute formal planning systems.

This led the authors to articulate the components of the rules for demand-driven materials requirements planning (DDMRP) and smart metrics. The authors describe demand-driven performance as dramatic lead-time compression and the alignment of efforts to respond to market conditions. This means forcing a shift from the push-and-promote model of operation to what is known as position and pull.

The authors describe smart metrics as system-flow based and not unit-cost based. Smart metrics focus on the visibility of relevant information, in a relevant time frame, to direct action and align priorities across the organization.

They focus on the rate of flow through the system, how to identify what is blocking it and the actions needed to remove it. They focus on system stability and reliability, which results in a high due-date performance. Smart metrics produce visible, easy-to-understand signals to reduce contention and eliminate conflicts for resources and material.

The book is divided into three sections. The first section states the problem and sets the framework for managing the organization. Section two gives history explaining how convention has resulted in a current suite of metrics that often lead an organization in the opposite direction. Finally, the last section offers readers a new direction to take with supply chains and smart metrics that focus on the strategic control points and decoupling points. DDMRP is to be used for formal planning, and smart metrics promise to keep those changes sustainable and scalable in a volatile and complex world.

Wayne Sander
Dousman, WI

RECENT RELEASES

Process Improvement Simplified: A How-to-Book for Success in Any Organization

James B. King, Francis G. King and Michael W.R. Davis, ASQ Quality Press, 2014, 192 pp., $30 member, $50 list (book).

The AS9100C, AS9110 and AS9120 Handbook: Understanding Aviation, Space, And Defense Best Practices

James Culliton, ASQ Quality Press, 2014, 204 pp., $45 member, $75 list (book).

Curve Your Enthusiasm

How to plot OC curves in Excel

SAMPLING PLANS are valuable in many quality control applications. But it can be difficult to explain the benefits of different plans to colleagues who are unfamiliar with the terminology. It is useful to show operating characteristic (OC) curves to facilitate those discussions. Many sources of OC curve images are inconvenient ("my books are on my desk"), or they are not relevant to the situation at hand (a published curve for a sample size of 70, but not for 68 or 75).

Fortunately, Microsoft Excel includes built-in functions that make drawing OC curves easy. In this column, we'll focus on attribute (pass/fail) single sampling plans that can be modeled with the binomial distribution, such as ANSI/ASQ Z1.4:2008. Excel can be used for other distributions, such as Poisson and hypergeometric, in a similar manner.

Figure 1 shows an example OC curve. It shows the probability of the sampling plan accepting the lot (on the y axis) based on the actual (and usually unknown) percentage of nonconforming items in the lot (on the x axis). Two values are required to draw the curves: sample size (n) and accept number (c). The accept number is the maximum number of nonconforming units that may be found in the sample for lot acceptance. To put it another way, the lot would be rejected if $c + 1$ or more samples are nonconforming. In the example spreadsheet in Figure 2, the user would enter values for n and c in cells B2 and B3 respectively.

The x axis lists possible values with the actual percentage of nonconforming parts in the lot. In Figure 2, values for the x axis are in column A, starting in row six. Smaller percentages are closer together to draw a smoother curve.

Y axis values for the OC curve are in column B, starting in row six. These values represent the probability of accepting the lot given n, c and the actual percentage of nonconforming parts (from column A). The probability to accept the lot comes from the binomial distribution. In Excel, the function to calculate this is:

=BINOMDIST(c, n, actual % nonconforming, TRUE)

You can substitute the cell references using cell B6 as an example:

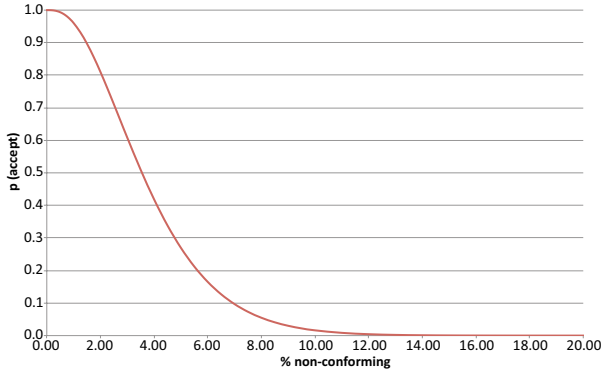
=BINOMDIST(B3,B2,(A6/100),TRUE)

Because the values for c and n will always be in cells B3 and B2, $ symbols are used to fix those cell references so they will not change when cell B6 is copied down to complete the table. The reference for the actual percentage nonconforming (A6) does not need the $ because it must change for every row (for example, in row seven it needs to be A7 instead of A6).

The percentage nonconforming also must be converted to a proportion (by dividing by 100) for the function to work correctly. Complete the table by copying cell B6 down to match the length of column A. Then, draw the OC curve by creating an xy chart using columns A and B (both starting in row six). Remember that the y axis is shown as a proportion, not a percentage.

OC curves provide a graphical method of comparing various plans in a way that is easy to explain. Excel makes it simple to create custom plans to meet specific requirements. Online Figure 1, for example, compares plans designed to allow lots that are 8% nonconforming to be accepted no more than 10% of the time. QP

Example OC curve (n = 75, c = 2) / FIGURE 1



Part of spreadsheet that created Figure 1 / FIGURE 2

	A	B	C	D
1				
2	n =	75		
3	c =	2		
4				
5	% non-conforming	p(accept)		
6	0.00	1.00000		
7	0.10	0.99994		
8	0.20	0.99951		
9	0.30	0.99845		
10	0.40	0.99651		
11	0.50	0.99354		
12	0.60	0.98942		
13	0.70	0.98407		
14	0.80	0.97744		
15	0.90	0.96952		
16	1.00	0.96033		
17	1.25	0.93198		
18	1.50	0.89670		
19	1.75	0.85565		
20	2.00	0.81013		
21	2.25	0.76147		
22	2.50	0.71091		
23	2.75	0.65954		
24	3.00	0.60833		
25	3.50	0.50939		
26	4.00	0.41861		
27	4.50	0.33842		
28	5.00	0.26966		

DAVID PHILLIPS is a senior quality engineer at Dentsply Caulk in Milford, DE. A senior member of ASQ, Phillips is a certified quality engineer and a Six Sigma Black Belt. He holds a bachelor's degree in mechanical engineering from Grove City College in Pennsylvania.

What's Online in the ASQ Knowledge Center?

CASE STUDY

Clean Approach Saves Global Pharmaceutical Drug Manufacturer Time, Money

A Lean Six Sigma project team at Mallinckrodt Pharmaceuticals used process mapping, root cause analysis, and other tools to create a new equipment cleaning procedure, reducing cycle time and rework while generating annual cost savings.

WEBCAST

Quality Snapshot: Documents and Records

In his Snapshot series, Mark Ames tackles commonly misunderstood topics related to quality and standards. This first installment clears the confusion about what a "document" is versus a "record."

BENCHMARKING

How Shingo Prize Winners Manage Their Supply Chains

This study examines the lean supply chain practices of Shingo Prize winners and includes case studies on Lycoming Engines, Rexam PLC, and US Synthetic.

Access this month's featured content and more Web exclusives in the ASQ Knowledge Center at asq.org/knowledge-center/featured.html.

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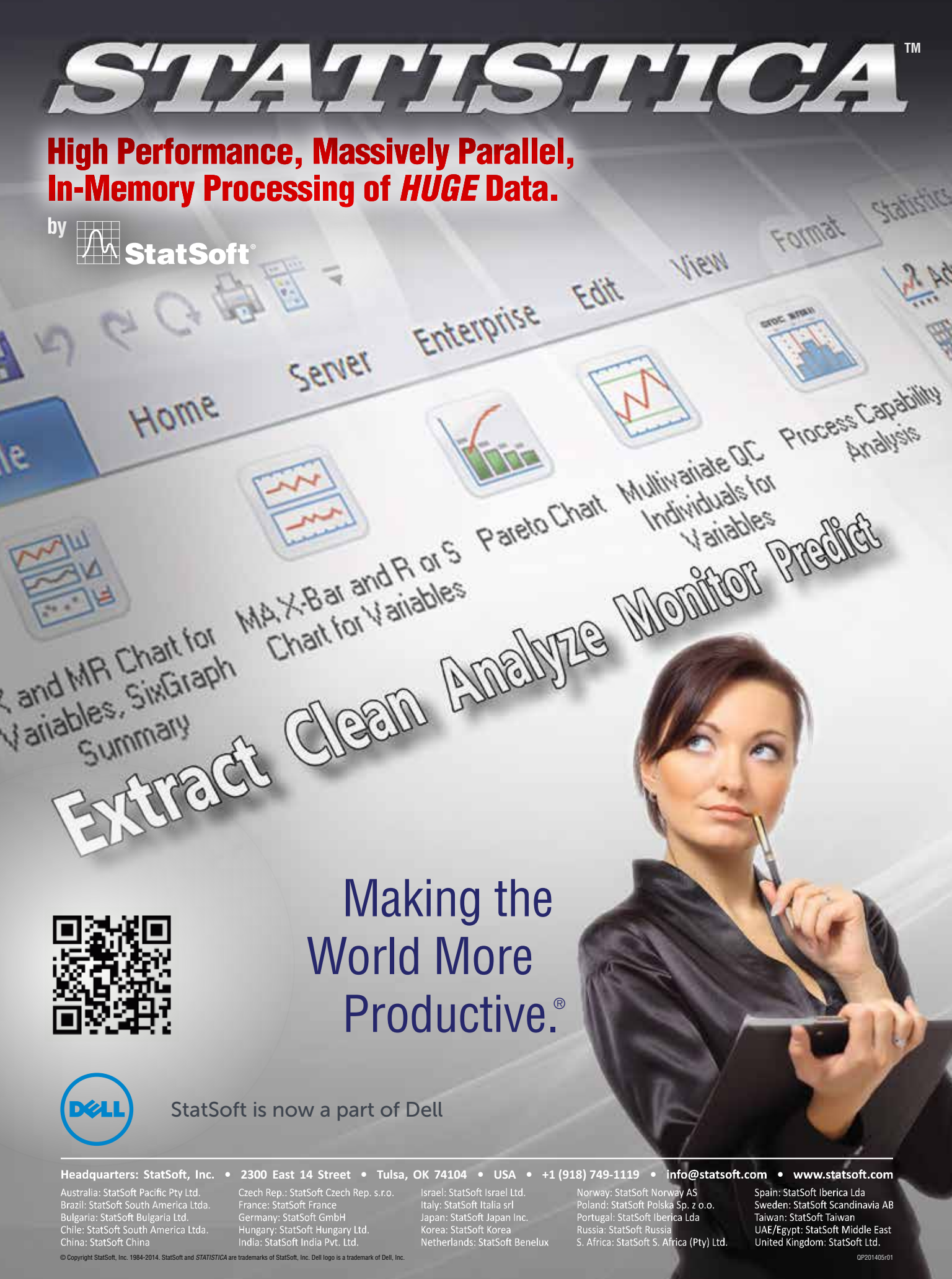

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