APRIL 2018 | QUALITYPROGRESS.COM

CELEBRATING 50 YEARS * CELEBRATING 50 YEARS * CELEBRATING 50 YEARS *

QUALITY PRO

The official

Sampling Strategies

Fresh approaches to process monitoring for product quality

ASQ
The Global Voice of Quality®

QUALITY PROGRESS | APRIL 2018 PRODUCT SAFETY VOLUME 51 | NUMBER 4

Quality Management Software

Improve the Way You Manage Quality and Track Risks

EtQ's flexible compliance platform provides you with the visibility and control to manage quality, EHS, and risk. Whether you're enterprise or mid-market, EtQ has the solution to meet your company's unique needs and provide you with the tools needed to make better decisions and ensure continual improvement.

www.etq.com • info@etq.com • 800.354.4476

EtQ

Visit us at booth 219 at the ASQ World Conference on Quality and Improvement.

UPCOMING CERTIFICATION EXAMS

- Calibration Technician
- Pharmaceutical GMP Professional
- Quality Auditor
- Quality Engineer
- Quality Improvement Associate
- Quality Process Analyst
- Six Sigma Green Belt
- Software Quality Engineer

GET YOUR ASQ CERTIFICATION

Looking for a way to stand out in 2018? ASQ certification can help with just that. Choose from 18 certifications that are sure to not only differentiate you from your competition, but can help result in a higher salary and help land a promotion. It's time to become a recognized expert in your field.

Apply for the June 2018 exams today!

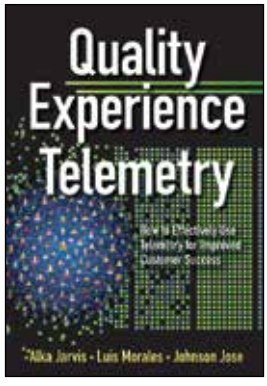
2018 | UPCOMING APPLICATION DEADLINE – May 4
TESTING WINDOW – June 1 – 17

For more information or to apply for an exam, **visit asq.org/cert**.

ASQ **50** Years of Certification
Quality Certifications Since 1968

CHECK OUT THE NEW BOOKS AVAILABLE FROM ASQ QUALITY PRESS!

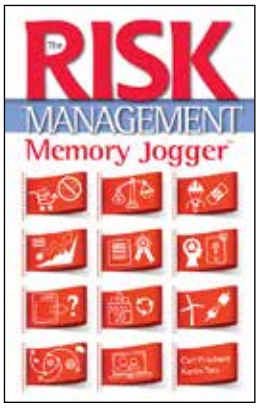
THIS MONTH'S PICKS!



Quality Experience Telemetry: How to Effectively Use Telemetry for Improved Customer Success

Telemetry is an automated way of collecting data at remote sites or locations, and transmitting it to collectors at receiving sites for monitoring, analyzing, and driving improvement actions. This groundbreaking book helps you understand the telemetry infrastructure and associated details, enabling you to implement a telemetry program to address customer pain and improve customer experience.

Item: H1542



The Risk Management Memory Jogger

Risk is everywhere. How do you decide whether the effort is worth the risk, or figure out how to minimize the risks? This guide will help you deal with the potentially rocky road of opportunity and risk. It begins with a roadmap and a five-step plan for how to proceed, including the "rules of the road" such as key terms, pitfalls to avoid, and tips that will keep you moving toward your goals.

Item: P1580

Learn more about these books through the Quality Press bookstore at **asq.org/quality-press**.

ASQ
The Global Voice of Quality®

FEATURES

QUALITY PROGRESS

INSIDE

April 2018
VOLUME 51 • NUMBER 4

EXCLUSIVES

at **qualityprogress.com**

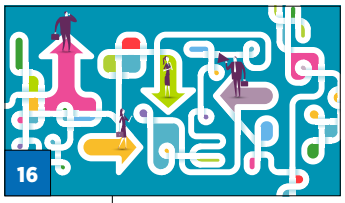
For Next Time
Retain QP content to read and reference later in the "My Saved Articles" repository.

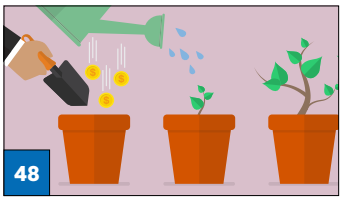
Pick and Choose
Review a selection of QP articles recommended by editors.

Talk Back
Provide feedback to authors and editors, and rate this month's four feature articles.

INSIDE

April 2018





QUALITY PROGRESS

Editor in Chief and Publisher
Seiche Sanders
@ASQ_Seiche

Associate Editor Mark Edmund
@ASQ_Mark

Assistant Editor Lindsay Dal Porto @ASQ_Lindsay

Manuscript Coordinator
Valerie Ellifson

Copy Editor Amanda Hankel

Art Director Mary Uttech

Creative Services Manager
Cathy Milquet

Graphic Designers
Cori Haagensen, Sandy Wyss

Advertising Production
Barbara Mitrovic

Digital Production Specialists
Julie Stroik, Julie Wagner

Media Sales Naylor LLC
866-277-5666

Editorial Offices 414-272-8575

Mail
Quality Progress/ASQ
600 N. Plankinton Ave.
Milwaukee, WI 53203

Telephone 800-248-1946
Fax 414-272-1734

Email editor@asq.org

Article Submission Process
Quality Progress is a peer-reviewed publication with 85% of its feature articles written by quality professionals. To learn more about article submission and the manuscript review process, visit www.qualityprogress.com under "Tools and Resources" and click on Author Guidelines.

Quality Progress (ISSN 0033-524X) is published monthly by the American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203. Editorial and advertising offices: 414-272-8575. Periodicals postage paid at Milwaukee, WI, and at additional mailing offices. Institutional subscriptions are held in the name of a company, corporation, government agency or library. Requests for back issues must be prepaid and are based on availability: ASQ members $17 per copy; nonmembers $25 per copy. Canadian GST #128717618, Canadian Publications Mail Agreement #40030175. Canada Post: Return undeliverables to 2835 Kew Drive, Windsor, ON N8T 3B7. Prices are subject to change without prior notification.

Postmaster: Please send address changes to ASQ, PO Box 3005, Milwaukee, WI 53201-3005.

Printed in USA.

FOREWORD

The quality inside *Quality Progress*

Safety Check

Getting serious about product safety

There are few times in life when the average person is more attuned to product safety than when raising an infant. Oh no! Could a piece break off her toy and choke her? Now that she's gnawing on it, do you think the paint on her crib is laden with lead? Is it just me, or does that wheel on her stroller look like it might suddenly snap off and catapult her into traffic?

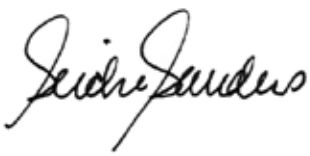
Many new parents (Who, me?) are beleaguered with irrational thoughts that something awful will happen to their helpless little darlings. But sadly, these fears aren't always irrational. Each scenario here is actually tied to a recent product recall. Scary stuff.

For folks in quality, product safety isn't limited to parental apprehension. For many, it is directly or indirectly your raison d'être, and so this month we bring focus to product safety and ways you can help deliver on it.

"Serious About Samples," p. 18, describes some of the advantages and disadvantages of sampling and statistical process control charts, and provides insights into a strategic approach to sampling based on the points at which inspections occur in a process. The approaches suggested here could put higher quality products in customers' hands.

In "Seeking Validation," p. 24, learn about the importance of process validation as it relates to medical device manufacturing. The tips and lists in this article can help any organization prepare for an inspector's questions and requests related to process validation procedures.

Finally, it's job report season, when the predictions roll out on what jobs will take the top spots for the workforce of the future. But no need to go scouring the web to track down the information. QP Associate Editor Mark Edmund has pulled many of the lists together into a comprehensive roundup beginning on p. 10. Do you hold one of the top job titles? Would you like to? Find out where the gaps and opportunities are in the job landscape of the future. QP



Seiche Sanders
Editor in Chief and Publisher

SEEN & HEARD

Reader reactions from around the world

PRACTICAL APPLICATION

In response to "Ready or Not" (January 2018, pp. 16-21): Many thanks, Govind Ramu, for sharing your years of hands-on experience implementing management systems. I found this article quite relevant, useful and practical. Practitioners can use it to improve or implement ISO 9001:2015.

Sunil Thawani, Abu Dhabi

GOOD RECOMMENDATION

I teach statistics and I think "Statistics Spotlight: Staying Relevant" (February 2018, pp. 53-57) is an interesting article that my students should read. I will definitely recommend it to them.

Carlos Dominguez, Chicago

TRICKY TOPICS

Key points of the ISO 9001:2015 transition are well summarized in "Ready or Not" (January 2018, pp. 16-21). The examples of the potentially tricky topics of "organizational issues" and "interested parties' identification and requirements" are especially helpful guidance.

Ferenc Nagy, Sunnyvale, CA

THE REACTION GAUGE

this month's question

Each year, organizations such as LinkedIn and the U.S. Bureau of Labor and Statistics publish their predictions for the top-trending jobs that year. Not surprisingly, the jobs topping these lists this year are related to data and software—data scientist, data security administrator, software developer and software engineer—and also healthcare.
What other changes have you noticed in the job market? Has your organization added—or eliminated—any jobs or departments that reflect these changes?

Send us your take at editor@asq.org. Or join the discussion on LinkedIn at www.linkedin.com/groups/3633.

last month's question

As organizations begin to realize just how important culture is to their employees and to the customer experience, more and more are adding a chief customer officer and chief culture officer to their C-suites.
Has your organization added either of these positions? If not, who is responsible for your organization's quality culture?

Steven Garner, Reno, NV, says:
While we absolutely should build quality into our products and services, it's much more than an old cliché to say that quality also should be a culture in our organization. When we say "quality," most people think of quality assurance, and there's nothing wrong with that, but we shouldn't stop there. What about the engineer who designs our products? Or the buyer who places the purchase order? What about the accounts payable technician who ensures our suppliers are paid on time? Quality is everyone and everything. It's more than just a function.

Samvit Mishra, Gurgaon, India, writes:
Care should be taken to ensure no artificial silos are created, to the extent that production or operations people start thinking that quality is somebody else's responsibility. Top management or the CEO should deploy and use a quality facilitation team, including probably a C-level executive, to drive quality from each employee of the organization. The key word is "each" employee!

Mike Adams, Miami:
I become concerned when there are suggestions that an enterprise's culture is relegated to a department. It must be from the top. A strong partnership between a quality leader and HR (provided HR has a strategic role) can serve and aid the CEO, but business units and silos only will move culture if they're expected or compensated to, or terminated for not supporting their leader.

ASQ
The Global Voice of Quality®

REGISTER ONLINE BY **April 25, 2018!**

asq.org/wcqi

The Innovation of **YOU**

"This was the first time I attended and got my inspiration back. I can honestly say it has been a life-changing experience. I believe in quality and how it can change people, lives, relationships, and so many other things. This conference was very satisfying."

WORLD CONFERENCE on QUALITY and IMPROVEMENT 2018

April 30 – May 2, 2018 | Seattle, WA

LEARN! Sessions and workshops will focus on:

- **QUALITY 4.0:** *The Future of Quality Starts Here*
- Risk and Change
- Building and Sustaining a Culture of Quality
- Quality Fundamentals in the Digital Age
- Master's Series

CONNECT! Use hashtag #WCQI2018 to meet, post, share, and view with other attendees using social media.

ENGAGE! Experience a variety of learning environments. Session formats include "TED-Style" Quality 4.0 Theater Sessions, Satellite Sessions outside of the convention hall, and less formal "After 5" Sessions between the facilitator and participants with a social component.

Visit asq.org/wcqi to register and learn more.

Q&A

Subject matter experts take on your quality-related queries

EXPERT ANSWERS

THIS MONTH'S FIRST QUESTION

I'm looking for advice about how best to implement a 5S strategy in a manufacturing environment. My organization attempted this years ago, but the effort slowly fell to the wayside. I have been tasked with trying to implement another 5S program, but I want to get everyone on board so it is successful. Any advice?

OUR RESPONSE

The success of any program depends on an approach that considers not only management but also the employees responsible for implementing the change.

From a management perspective, a clear framework and guidelines must be set (a top-down approach). For the employees involved in making the changes, the program guidelines and framework should translate into meaningful actions with sufficient motivation (a bottom-up approach).

Here, in no particular order, are a few practical ideas to consider:

+ Define the goals of the 5S program, such as reduce costs, reduce clutter, improve working environment, increase efficiency and instill a sense of pride. Management should receive these goals as part of its key performance objectives for the year.
+ Define clear time frames, such as, "by the end of the first quarter we will reduce X by Y%," and "by the end of the second quarter we will reduce Z by P%." Assign each change a dollar value.
+ Consult with shop employees and divide the shop floor into sectors. Assign a 5S leader to each sector and allow the leaders to choose their improvement teams, but ensure that the team sizes are appropriate.
+ Define meaningful and manageable chunks of work for each team, and measure performance against the objective at the end of each quarter.
+ Make the 5S program into a friendly competition between teams. Each quarter, award tangible prizes to the top three teams and consolation prizes for the others.
+ Every team member should contribute to the 5S effort. Develop a 5S checklist and post it in all workplaces. Each team leader also should post the aggregate scores of his or her team.
+ Every month, team leaders should present the changes they have implemented. This way, each team can see the changes and strategies other teams enacted and showcase the changes they have made, instilling pride in their achievements.
+ Appoint a 5S champion to coach and mentor the various teams. The 5S champion also should be responsible for auditing the scores derived earlier.
+ Develop an incentive plan for

the best performing team and celebrate with fanfare.

+ All team members should receive at least a day's worth of official training from an accredited institute. This training should be included as part of the employees' yearly training and development plans. Also plan an annual refresher course with possible industry-recognized certification after a certain number of modules are finished.
+ During the 5S rollout, ensure that every shop floor employee is invited. Distribute t-shirts or caps with a logo for the 5S project and display them prominently.
+ Visualize successes by displaying before and after pictures.
+ Ideally, also involve office employees in the 5S program so that unused files, furniture and equipment can be effectively removed.
+ Set aside about four hours every two weeks for mandatory 5S activities. Everyone must stop what they are doing to clean up.
+ Ensure that you set up enough waste disposal containers. Dedicate garbage bins to paper, cardboard, wood, metal and grease, for example. Have large unused or broken equipment removed and ensure that all discarded items are removed quickly.

This response was written by **Narahari Rao,** business process architect, Schlumberger, Houston.

THIS MONTH'S SECOND QUESTION

What is the difference between quality assurance and quality control?

OUR RESPONSE

Let's start by defining the terms. *ISO 9000:2015—Quality management systems—Fundamentals and vocabulary* defines the terms as follows:

+ **Quality assurance** is the "part of quality management focused on providing confidence that quality requirements will be fulfilled."[1]
+ **Quality control** is the "part of quality management focused on fulfilling quality requirements."[2]

Upon reviewing the definitions, there is one key difference in the statements: The definition of "quality assurance" contains the phrase "providing confidence."

But what does that mean? Assurance that the procedure or process will produce results that consistently meet regulatory and statutory compliance, or the customer's expectations of the product or service. Typically, that means preventing defects or nonconformances, or implementing an improvement opportunity, such as:

+ Procedures or processes that support a quality management system (QMS).
+ Procedures or processes that support the creation of a customer product or service.
+ Validating these procedures and processes.
+ Ongoing monitoring and correction of these procedures and processes.

Quality control, on the other hand, is the ability to detect whether the procedure or process conforms to the requirements through an inspection process, such as measurement and testing. These inspection processes are established at key points in the process to determine whether the process output meets the established requirements. Examples include:

+ Inspecting incoming raw material.
+ In-process testing.
+ Reviewing documents for completion and accuracy.
+ Reviewing and approving quality system records.

It may be easier to identify a quality control activity than a quality assurance activity. Quality control is a measurement taken at a specific moment in time to determine adherence to requirements—whether regulatory, statutory or customer-specific—and quality assurance is all other QMS activities. When in doubt, ask yourself: "What am I measuring?" If the answer to whether it meets compliance is "yes" or "no," then it is quality control activity. QP

REFERENCES

1. International Organization for Standardization (ISO), *ISO 9000:2015—Quality management systems—Fundamentals and vocabulary*, subclause 3.3.6.
2. Ibid, subclause 3.3.7.

This response was written by **Tiea Theurer,** lead auditor, TÜV Rheinland, Newark, DE.

THE PROGRESS REPORT

A digest of trends, research & late-breaking news

CAREERS

Jobs Report Roundup

Positions related to data, software and healthcare dominate hot jobs of 2018 and beyond

The results are in: If you hold a job or are considering one that deals with data and digits, you're probably in a good spot.

Usually around this time each year, a flurry of hot jobs lists are released by various employment firms, job boards and publications—each making their predictions on the most popular careers for the upcoming year or the near future. The rankings are based on a variety of factors, including salaries, open jobs and employee satisfaction. The U.S. Bureau of Labor and Statistics (BLS) gets in on the act, too.

Quality-related positions keep making their appearances on the various rankings: statisticians, risk managers and directors, audit managers, reliability engineers and process engineers, to name just a few.

But this year, you'll find that jobs dealing with number crunching, data and coding—different types of data experts and software developers—consistently dot the respective rankings. (Check out several recent job rankings throughout this article.)

The reason? Over recent years, organizations around the United States continue to collect larger and larger amounts of data about their customers, businesses and markets, experts say. Now, more talent—such as data scientists and data engineers—is necessary to help organizations decide what to do after they collect all that data, and what decisions to make.[1]

"Every company collects mountains of data: some valuable, most not," said Jay Samit, a vice chairman at technology consulting firm Deloitte Digital. "It's the data scientist's job to distinguish between the two."[2]

Data-related job titles getting extra attention these days include data scientist, database administrator, data engineer, data analyst, database analyst, database developer and data security administrator.

As long as technology remains as important as it is in work and social situations, software developers won't be going out of style anytime soon. Software

LinkedIn's Most Promising Jobs

1. Engagement lead
2. Software engineering manager
3. Customer success manager
4. Solutions architect
5. Sales director
6. Engineering manager
7. Program manager
8. Product manager
9. Data scientist
10. Enterprise account manager

Source: LinkedIn, https://tinyurl.com/linked-promising-jobs

U.S. News and World Report TOP 10 JOBS OF 2018

1. Software developer
2. Dentist
3. Physician assistant
4. Nurse practitioner
5. Orthodontist
6. Statistician
7. Pediatrician
8. Obstetrician and gynecologist (tie)
9. Oral and maxillofacial surgeon (tie)
10. Physician (tie)

Source: *U.S. News and World Report*, https://tinyurl.com/us-news-25-jobs

The 25 BEST JOBS for the Next Decade

1. Solar photovoltaic installers
2. Wind turbine service technicians
3. Home health aides
4. Personal care aides
5. Physician assistants
6. Nurse practitioners
7. Statisticians
8. Physical therapist assistants
9. Software developers—applications
10. Mathematicians
11. Medical assistants
12. Bicycle repairers
13. Physical therapist aides
14. Occupational therapy assistants
15. Information security analysts
16. Genetic counselors
17. Operations research analysts
18. Forest fire inspectors and prevention specialists
19. Health specialties teachers—postsecondary
20. Derrick operators—oil and gas
21. Physical therapists
22. Occupational therapy aides
23. Roustabout—oil and gas
24. Phlebotomists
25. Rotary drill operators—oil and gas

Source: Best Schools, https://tinyurl.com/best-schools-job-list

CareerCast's TOP 10 TOUGHEST JOBS TO FILL in 2018

1. Application software developer
2. Construction laborer
3. Financial advisor
4. Home health aide
5. Information security analyst
6. Medical services manager
7. Nurse practitioner
8. Personal care aide
9. Physical therapist
10. Truck driver

Source: CareerCast, https://tinyurl.com/career-cast-jobs-list

CNN/Payscale.com's Top 10 Best Jobs in America

1. Mobile applications developer
2. Risk management director
3. Landman
4. Product analyst
5. Information assurance analyst
6. Quality assurance coordinator (RN)
7. Clinical applications specialist
8. Hospital administrator
9. Database analyst
10. Finance and administration director

Source: CNNMoney/PayScale.com, https://tinyurl.com/cnn-money-best-jobs.

developer-types are the ones who create, maintain and fix applications and programs for smartphones and computers, paying attention to function and form.[3]

"Our society is more and more dependent on digital technology for all aspects," said Rebecca Koenig, a contributor to an analysis done by *U.S. News and World Report.* "Not just Facebook and Google, but every other business needs software developers to make their applications. Even hospitals are tapping into digital communication to make sure doctors and patients can communicate."[4]

Software-related job titles listed as top jobs include software engineering manager, software developer, software engineer, application software developer and mobile applications developer. In fact, application software developer also is ranked as the toughest job to fill in 2018, according to CareerCast.[5]

Constant healthcare demand

Of course, healthcare jobs are never going away, and they have dominated the top rankings over the past decade. Many of these jobs continue to thrive on the various hot jobs lists. In fact, healthcare jobs are expected to grow 18% by 2026, according to data from the BLS, adding 2.3 million new jobs, more than any other industry. That trend is mostly linked to the large population of aging baby boomers who will need care in the coming years.[6]

Healthcare jobs may be some of the most difficult to fill, however. Healthcare positions make up half of CareerCast's top 10 toughest jobs to fill in 2018: home health aides, medical services managers, nurse practitioners, personal care aides

continued on page 12 ▸

Jobs Report Roundup

▸continued from page 11

and physical therapists. Non-healthcare positions on the list include application software developers, construction laborers, financial advisors, information security analysts and truck drivers.[7]

Overall, the demand for data specialists, software developers and healthcare workers will continue in the foreseeable future.

"One thing we are noticing across the board is these jobs aren't in danger of being automated," said Glassdoor spokeswoman Sarah Stoddard. "The combination of technical and soft skills really plays well in the workplace."[8]

Jobs in jeopardy

Between 400 million and 800 million of today's jobs, however, will be automated by 2030, according to a new study by economic think tank McKinsey Global Institute.[9]

Those most vulnerable? The middle class, the McKinsey report said. Office administrators and construction equipment operators are among those who may lose their jobs to technology or see their wages depressed to keep them competitive with robots and automated systems.[10]

The World Economic Forum estimates that about 57% of the displaced will be women, who largely dominate the administrative roles that are at high risk from automation.[11]

New jobs also will appear, including even more demand for caregivers and healthcare-related workers to tend to the aging population.[12]

"There will be enough jobs for all of us in most scenarios," said Susan Lund, a co-author of the McKinsey report.[13]

—compiled by Mark Edmund, associate editor

EDITOR'S NOTE
References listed in this article can be found on the Progress Report webpage at **qualityprogress.com.**

Glassdoor's 25 BEST JOBS in America

1. Data scientist
2. DevOps engineer
3. Marketing manager
4. Occupational therapist
5. HR manager
6. Electrical engineer
7. Strategy manager
8. Mobile developer
9. Project manager
10. Manufacturing engineer
11. Compliance manager
12. Finance manager
13. Risk manager
14. Business development manager
15. Front-end manager
16. Site reliability engineer
17. Mechanical engineer
18. Analytics manager
19. Tax manager
20. Creative manager
21. Software engineer
22. Hardware engineer
23. Corporate recruiter
24. Quality assurance manager
25. Physician assistant

Source: Glassdoor, https://tinyurl.com/glassdoor-job-list.

Mr. Pareto Head By Mike Crossen

CUSTOMER SATISFACTION

SURVEY: Bank Customers Want More Financial Advice

The majority of U.S. retail bank customers say they are interested in receiving financial advice or guidance from their bank, according to a recent J.D. Power study, but just a small percentage of those customers say they actually receive that advice, a missed opportunity for banks to provide a needed service and possibly enhance customer satisfaction efforts.

"In recent years, large U.S. retail banks have steadily improved customer satisfaction because of technology investments to provide greater banking convenience and more-consistent products and services," said Paul McAdam, senior director of the banking practice at J.D. Power. "The challenge for banks is getting the advice formula right and delivering it in a personalized manner across all channels—not only at the branch but also via the website and mobile app."

Among the key findings from the study released in late February:

- 78% of retail bank customers want guidance.
- Customers believe they benefit from advice. In fact, 89% of customers said they believe they have benefited from the information.
- Many banks are missing a big opportunity to connect with customers. Only 28% of customers said they can recall recently receiving any type of financial advice.
- Banks struggle to deliver advice digitally.
- Millennial customers are among the most receptive customers to receive bank advice.

The inaugural study measured retail banking customer satisfaction with 17 large U.S. banks, as well as best practices related to retail bank-provided advice and account opening processes. **For more from the study, visit https://tinyurl.com/jdpower-bank-customers.**

News Brief

The Baldrige Performance Excellence Program will be honored this year for providing top-ranked leadership development programs. The Baldrige Program's training offerings—the annual Baldrige examiner training and the Baldrige Executive Fellows Program—were recently selected for 2018 Leadership Excellence and Development awards for being among the best in the world. For more information about the honors, visit https://tinyurl.com/baldrige-programs-honored.

GETTING TO KNOW...

Donald C. Singer

current position

Managing an expert team in microbiological control of a sterile pharmaceutical operation at GlobalSmithKline (GSK).

education

Master of science degree in applied biology and biology from the University of Dayton in Ohio.

What was your introduction to quality?

My introduction to quality was as a subject matter expert performing an audit of an egg albumin supplier in Arkansas. It was the beginning of a long career and exposure to quality in many different forms and cultures.

Do you have a mentor who has made a difference in your career?

A former supervisor encouraged me to stretch beyond my day job to network with others who were experts in the field. He encouraged sharing of knowledge to gain trust and respect in science.

What's the best career advice you've received?

Be yourself, develop relationships based on trust and don't give in to anything less than honesty and integrity.

Any previous jobs you consider noteworthy?

As a supervisor at a food company, over a five-year span I had multiple roles including quality control lab supervisor, sanitation engineer, industrial engineer, pest management tech, supplier auditor and quality assurance supervisor. What a learning experience!

Are you active in ASQ?

Active member of ASQ's Professional Qualifications and Ethics Committee, Liaison to Technical Communities Council Administrative Committee, member of the ASQ Examining Committee, and member of ASQ Food Drug and Cosmetic Division.

Any recent honors or awards?

Elected an ASQ fellow and a GSK fellow in 2017.

What noteworthy activities or achievements outside of ASQ do you participate in?

I am a member of the Microbiology Expert Committee in the United States Pharmacopeia. I also participate on task groups by writing technical documents for the Parenteral Drug Association and the European Biopharmaceutical Enterprises. I have completed more than 60 sprint triathlons. I enjoy the multisport combination because it is mentally and physically challenging, which is a thrill. In 1989, a friend challenged me to try the multisport event instead of simply participating in running events. After I finished my first one, I was hooked. My goal for each event is to be consistent, stretch my capacity a little more, and finish it.

Have you had anything published?

I have co-authored three books and several articles.

Personal:

Married to Sue, with a daughter, son and one grandchild.

What books are you currently reading?

Just finished *Rattling the Cage* and started *Blue Ocean Switch*.

Quality quote:

Quality is a culture, a mindset. The customer should always have input because they make the final judgement.

ASQ

World Conference Speakers Announced

Event organizers are finalizing details for this year's ASQ World Conference on Quality and Improvement (WCQI) April 30 to May 1 in Seattle. Keynote speakers scheduled for the event are:

+ **John McElligott, president of the Fortress Initiative, CEO of the Fortress Academy and CEO of York Exponential, a technology company that develops and leverages robotics, machine learning and artificial intelligence. He is known as a vision caster and technical futurist.**

+ **Mel Robbins, an entrepreneur, author and social media influencer. She's also a motivational speaker, and her TEDx talk about change has been viewed more than 10 million times. Her latest book is titled *The 5 Second Rule.***

+ **Luke Williams, author and expert on disruptive technology. He is a professor of marketing at NYU Stern School of business and the founder and executive of the W.R. Berkley Innovation Labs. He is the author of Disrupt: Think the Unthinkable to Spark Transformation in Your Business.**

Visit asq.org/wcqi for more information about the keynote speakers and other activities planned at the three-day conference.

New @ ASQ

What's on our minds

QUALITY RESOURCES **Access to ASQ's extensive collection of quality information and resources is readily available through ASQ's Advanced Search database, found at http://asq.org/knowledge-center/search/ This database includes books, articles from ASQ's eight periodical publications, conference proceedings, standards, case studies, and benchmarking information. In addition, ASQ's research librarian is available to assist members with their research needs. In order to request customized research assistance, please complete the form found here: https://asq.org/quality-resources/ask-a-librarian or send an email to knowledgecenter@asq.org.**

14 THOUGHT LEADERS TO BE HONORED

At ASQ's World Conference on Quality and Improvement, ASQ will present its Distinguished Service Medals and other society medals and awards. The 14 medal and award recipients are:

+ **Distinguished Service Medal: Janet Raddatz, Sargento Foods Inc., Plymouth, WI; and Steven Paul Bailey, Steven P. Bailey LLC, Wilmington, DE.**
+ **Feigenbaum Medal: Ali Masoudi, U.S. Business Council for Sustainable Development, Austin, TX.**
+ **Shewhart Medal: Christine M. Anderson-Cook, Los Alamos National Laboratory, Los Alamos, NM.**
+ **Shainin Medal: Cristobal Samaniego, Ann Arbor, MI.**
+ **Lancaster Medal: Daniel Edward Sniezek, Lockheed Martin (retired), Binghamton, NY.**
+ **Crosby Medal: Elizabeth A. Cudney, Missouri University of Science and Technology, Rolla, MO; and Tina Kanti Agustiady, InnovaNet, Tampa, FL.**
+ **Hromi Medal: Gary K. Griffith, Griffith Training, Corona, CA.**
+ **Grant Medal: James E. Breneman, Engineering & Quality Solutions, Easley, SC.**
+ **Hutchens Medal: KoAnn Vikoren Skrzyniarz, Sustainable Brands, San Francisco.**
+ **Edwards Medal: Linda Westfall, Westfall Team Inc., Montague, TX.**
+ **Brumbaugh Award: Heng Su, Wells Fargo, Charlotte, NC; and C.F. Jeff Wu, Georgia Institute of Technology, Atlanta.**

QUALITY HEADLINES

QUALITY NEWS TODAY FROM AROUND THE WORLD

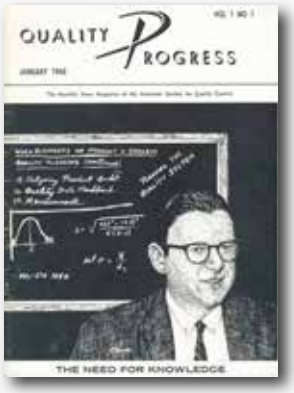
-powered by Lexis Nexis

"Microsoft's Changing Corporate Culture Brings Back Former Employees." Under past management, Microsoft had become known as an organization mired in internal competition among managers, teams and employees. It also pitted employees against each other in annual reviews, a system, since changed, that had faced widespread criticism from employees. This internal competition, some believe, diverted Microsoft's attention away from competing against Apple, Google and other rising giants of the 2000s. But since Satya Nadella took the reins as CEO in 2014, things are starting to turn around. **Read more here:** https://tinyurl.com/ycfmfmna.

"Twitter Tweaks Direct Messaging for Better Customer Service." In a bid to make customer experiences better on Twitter, the microblogging site has relaxed the rules for customer service direct messages (DM) and introduced a new feature that makes sure businesses can always respond to the customers' DMs. **To learn more, visit** https://tinyurl.com/yczpdcmh.

"Porsche First to Successfully Test Blockchain in Cars." Porsche is the first auto manufacturer to implement and successfully test blockchain in a vehicle. The applications tested include locking and unlocking the vehicle via an app, temporary access authorizations and new business models based on encrypted data logging. **Read the full story at** https://tinyurl.com/yamjwotf.

For a weekly roundup of the most noteworthy stories, subscribe to the *QNT Weekly* e-newsletter at asq.org/newsletters.



EDITOR'S NOTE: *To mark the 50th anniversary of the debut of* Quality Progress *in January 1968, editors will occasionally highlight a different element of the magazine throughout its history. This month, we bring back a photo from the magazine's news digest—originally titled "News You Might Need"—from January 1968.*

NEWS YOU MIGHT NEED

QC METHODS AIRED AT VILLANOVA

Among the participants at the 11th Annual Symposium on Quality Methods held at Villanova University by the Philadelphia Section were Ben S. Seward, program chairman; Charles A. Cianfrani, chairman; Paul R. Krauss, vice chairman; and Art W. Kane, secretary-treasurer of the symposium committee. Luncheon speaker Dr. A. V. Feigenbaum spoke on "Quality's Place in Industry."

Advice to advance your career

CAREER COACH

PERSONAL QUALITY

The Path to Personal Quality

Use personal strategic planning to achieve your career goals

by Jamison V. Kovach

Studies show that there are three keys to success in life: self-confidence, perseverance and a tendency to set goals. We all want to be successful, but it's often particularly challenging to set and achieve personal goals.

We see organizations successfully achieve their goals all the time using *hoshin kanri* and other strategic planning methods, so why does strategic planning at a personal level pose such a challenge? Perhaps it's because we're not as familiar with approaches to personal strategic planning as we are with methods for organizational strategic planning.

Like many other approaches, personal strategic planning can be broken down into five concrete steps:

1. Define your values.

Some helpful questions to ask yourself in this phase of the planning process are:

+ What do I value?
+ What roles do I play (at work and at home)?
+ What do I want (short and long term)?

It's important to note that developing answers to at least a couple of these questions requires some soul searching, so give yourself enough time to reflect on these questions in detail and develop comprehensive answers.

2. Understand what's important.

There's just one question to answer in this step, but it's critical to the planning process: What is valued in my (work or home) environment? Perhaps at work, it's the number of projects you complete each year. At home, maybe it's the amount of quality time you spend with your family.

If you don't know what's valued in your environment, spend some time asking others and make a list. Doing so is crucial to your success.

3. Identify your goals.

After you've identified your values and what is valued in your environment, completing the next step of the planning process is relatively straightforward. But don't confuse straightforward with easy—identifying your specific personal goals can be challenging.

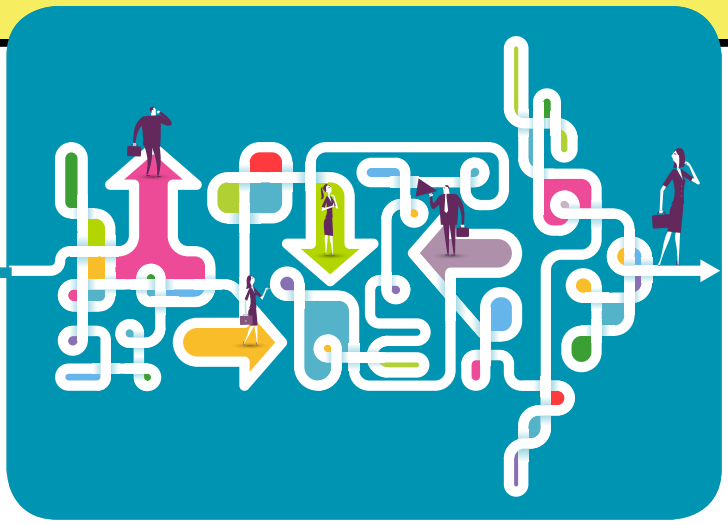
The clarity you develop regarding what you value and what's valued in your environment will make this step somewhat easier. Start by reviewing your list of what's valued in your environment and brainstorm what you'd like to accomplish in each of those areas while also keeping your values in mind.

Try to develop a list of four to six goals to guide your planning efforts. In addition, it's often helpful to focus on goals and activities that don't have built-in accountability. In other words, there are no checks and balances in your environment to ensure you do these tasks—because often these goals are the hardest to accomplish.

With that in mind, the remaining two steps in the planning process will help you hold yourself accountable for working toward achieving your goals.

4. Schedule tasks.

This step can be broken down into two parts that address how and when you plan to achieve your goals. First, brainstorm the specific tasks you must complete



over time to reach each goal.

Second, construct a high-level plan or schedule that identifies when you will complete each specific task. This plan can be set up as a simple table that outlines the next three to six months with tasks inserted in the appropriate weeks to denote when you plan to work on and complete those tasks.

Sometimes, tasks take longer than expected or are delayed by other things. So as things change, simply revise your plan as needed. Your plan can and should be a living document used to guide the achievement of your goals.

5. Work the plan.

The final step is to put your plan into action. To do that, schedule a 30 to 60-minute weekly planning meeting with yourself toward the end of each week. Some people like to do it on Friday afternoons and others prefer Sundays. Do whatever works best with your schedule, but make a firm commitment to yourself to hold this meeting each week.

The key is to spend time at the end of each week planning your schedule of tasks for the following week. This step involves scheduling the tasks developed in step four by identifying the specific days and times you will work on that week's tasks, as outlined in your high-level plan.

This ensures you don't waste time on Monday mornings figuring out what must be done that day and week. You simply can jump right in and start working on the first task you have scheduled.

Keep in mind that things will change, so be forgiving and flexible. If an unexpected request arises that requires your immediate attention, just shift things around in your schedule to accommodate the change as best as you can.

The last part of this step is to evaluate your recent performance and adjust your goals as needed. To effectively assess your performance and make adjustments, ask yourself:

+ Did I complete all my planned tasks for the week?
+ If not, what's holding me back?
+ What adjustments am I going to make moving forward?

These questions are a powerful way to check your progress toward achieving your goals each week, identify internal and external resistance that may be inhibiting your progress, and determine how to adjust your plan to make more progress going forward.

Recovering from failure

Of course, your personal strategic plan won't go perfectly every week, and that's OK. To combat the inevitable, be proactive and plan for failures. Build into your plan additional ways to hold yourself accountable. Don't skip your weekly progress assessments, and tell others about your goals and progress: Studies show that you are more likely to achieve your goals if you do.

Midterm review

In addition to weekly progress assessments, it also is helpful to conduct a midterm review about halfway through your plan. Some helpful questions to ask yourself at this point are:

+ What goals have (and haven't) I accomplished so far?
+ How consistent have I been in my daily work routine?
+ When, where and how have internal and external resistances affected my plan?
+ Is my current support system effective? If not, what additional things am I willing to try?
+ How do I feel about my answers to the previous questions?

Again, this series of questions is quite powerful in terms of keeping you on track or getting you back on track with your plan.

In the end, having a personal strategic plan will help you reduce wasted time and frustration trying to identify in real time what you must do each day and week, and it will provide a clear path to improved personal productivity and success in your career and life. QP

Jamison V. Kovach is an associate professor at the University of Houston in Texas. She holds a doctorate in industrial engineering from Clemson University in South Carolina. Kovach was awarded ASQ's Feigenbaum medal in 2010 and promoted to a full Academician in the International Academy for Quality in 2015. Kovach received her lean Six Sigma Black Belt certification from North Carolina State University in Raleigh. She is a senior member of ASQ and past chair of ASQ's Houston Division.

Serious About Samples

Understanding different approaches for process monitoring and when to use them | **by Manuel E. Peña-Rodríguez**

Sampling is one of the most-used methods in quality systems to control the output of any given process. Specifically, sampling allows organizations to distinguish between good product and defective product. In this way, defective product is rejected, while good product continues through the production stream.

One of the most-discussed topics in sampling is sample size. There are many methods used to determine the size of the sample. There is, however, another important aspect of sample selection: representativeness of the samples.

To be representative, a sample must have the same chance of being collected as the other samples do. Suppose that a sample size is calculated as 32, for example. Obtaining a representative sample would mean collecting four samples every hour during an eight-hour shift.

A non-representative sample would be obtained if you collected the first 32 samples of the shift or the last 32 samples of the shift. Using the first approach (four samples every hour), it would be easier to detect defects if they occur randomly throughout the shift. Sampling only at the beginning or end of the shift, however, makes it difficult to detect defects if they happen randomly throughout the shift.

An example would be sampling labels in a continuous

Just the Facts

Determining the sample of product is an important consideration for most organizations when they are trying to distinguish between good and defective product.

There are different sampling approaches for the inspection stages: incoming, in-process and final inspections.

By implementing these approaches, organizations can improve their inspection activities and provide better product to customers.

roll of paper. If an organization just takes a sample either at the beginning of the roll or at the end of the roll (or both), how would it be possible to detect defects somewhere in the middle of the roll? Even adding a sample in the middle of the roll might not be enough.

What will happen if, at three-quarters of the roll, there is a power failure that causes the printer to lose the programming? If you wait until the next sample at the end of the roll, it would be too late. For that reason, another sample should be collected after any planned (or unplanned) interruption of the process.

Sampling vs. SPC

Sampling is an easy and cost-effective way to monitor a process. The main disadvantage of sampling is that it does not provide much information about the quality level of the process. It only provides binary information: good product or defective product.

It does not tell you how good the product is or how bad the defective product is. Based on the traditional concept of variation explained in Genichi Taguchi's loss function (see Figure 1), most organizations measure their product quality against specification limits. If the process is within the upper and lower specification limits, the process is assumed to be good and nothing else is done (left side of Figure 1).

But Taguchi explained that this is not a good approach. Losses start to develop as soon as you deviate from the target value (right side of Figure 1). Taguchi calculated the losses using the formula:

$$L = k(y - T)^2$$

in which L is the monetary loss, k is a cost factor, y is the actual value and T is the target value.

Based on Taguchi's loss function, if you want to reduce the losses, you must focus on variation—specifically, on reducing process variation.

From the formula, it means that the output value (y) must be as close as possible to the target value (T). As noted earlier, sampling does not tell you about the variation of the process. It only allows you to determine whether the product is accepted (good product) or rejected (defective product).

So, if you want to learn about process variation, you should not rely only on acceptance sampling. You must have a more dynamic approach. A good method is statistical process control (SPC) using the control chart.

A well-known assumption is that all processes are subject to some kind of variation. The two main types of variation are common-cause variation and special-cause variation:

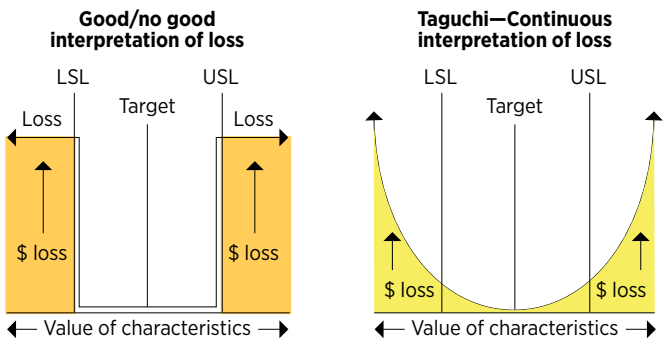
- **Common-cause variation** is present in every process because no process is perfect. It is inherent in every process.
- **Special-cause variation** is not present in every process and is caused by assignable events—that is, by certain things that have a significant impact on the process.

In a control chart, the control limits define where the common causes of variation are expected to lie. In other words, as long as the process is in statistical control, all the points will lie within the control limits defined by the interval of ±3s from the mean, without any nonrandom pattern. When you see a point outside of those control limits (or points showing a nonrandom pattern), that indicates some sort of assignable or special cause that must be studied and corrected.

A control chart not only allows you to see how the process centering and variation behave on a time-based scale, but it also allows you to see the result of some process improvements. Figure 2 shows an example of a control chart in which process improvements have been implemented. Note that because the control limits are calculated based on the process variation, when variation decreases, the control limits must be recalculated to reflect the new, lower variation.

FIGURE 1

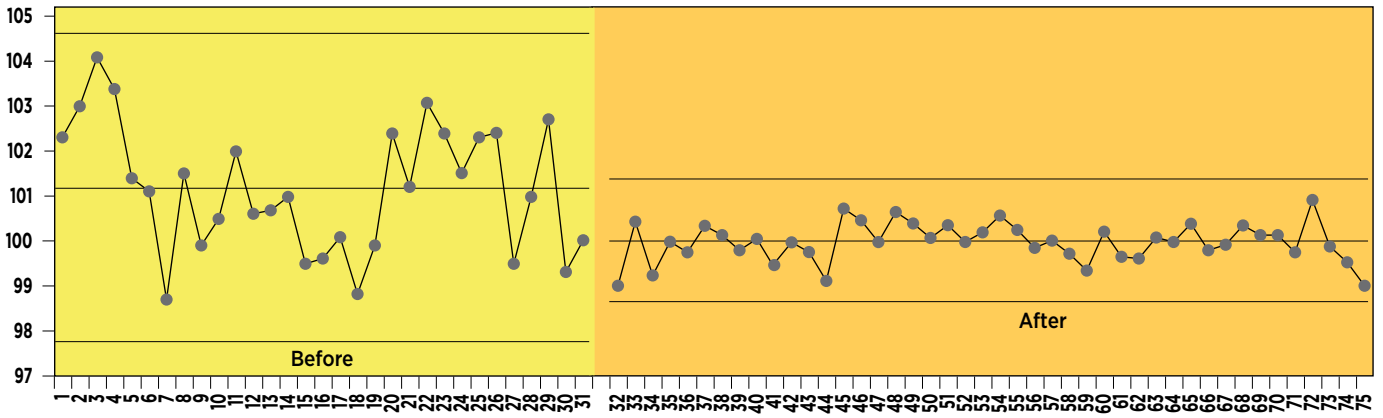
Concepts of process variation as compared to customer specifications



LSL *= lower specification limit*
USL *= upper specificaion limit*

FIGURE 2

Control chart—before and after improvements



Recommended approaches at various stages

Now that you know some of the advantages and disadvantages of sampling and SPC control charts, let's explore when it is convenient to use sampling and when it is convenient to use control charts to monitor the quality of the process. Let's divide the inspection location into three areas: incoming, in-process and final.

Incoming inspection: At this part of the process, the organization is receiving raw materials, packaging materials, purchased components and so on. It is important to measure the quality of the materials at this stage to avoid accepting defective product that will cause problems downstream.

But what is the best approach at this stage of the process? As noted earlier, acceptance sampling is an easy and cost-effective way to assess the quality of the incoming product. Acceptance sampling plans—such as the ANSI/ASQ Z1.4 (for attribute data) and ANSI/ASQ Z1.9 (for variable data)—are common approaches at this stage.

The main disadvantage of these acceptance sampling plans is that, depending on the acceptance quality limit (AQL) values selected, you could have a plan that will accept the entire lot even with one or more defective parts. But this is not a major constraint at this stage. Why?

Because the processes must have enough controls to detect all those defective parts that were not detected during the incoming inspection process and reject them during the subsequent process steps. These acceptance sampling plans are designed to provide a high probability of acceptance if the percentage defective is at or below the established AQL. In other words, these plans provide a safeguard to the supplier of the incoming material because you would be still accepting the lot even with a small number of defects.

In-process inspection: There are many approaches that organizations use to inspect product while the process is going on. For example, many organizations

The main disadvantage of sampling is that it does not provide much information about the quality level of the process. It only provides binary information: good product or defective product.

use acceptance sampling plans, such as the ANSI/ASQ Z1.4. Other organizations develop some sort of sampling and establish alert limits and action limits to determine the course of action after the sample is collected.

The main problem with these approaches is that the decision is still pass/fail (continue the process or stop the process and make some adjustments). Typically, the reaction is too late. Another disadvantage of this type of approach is that it does not have memory—that is, each day's decision is taken, but it is registered only on that day's documentation. In this case, because the data are not recorded in a time-based scale, there is no way to see any possible trend. A solution to this dilemma is to record the data and plot it in a control chart.

For example, an organization might be sampling parts at a specific station using the alert limit/action limit approach. At the end of the day, if nothing out of the action limit happens, the organization just archives the form containing the number of defects for that day. If there is an out-of-the-action-limit event, the organization adjusts the process, records the amount of defects and also archives the form. However, nothing else happens.

The recommendation to this organization is to plot the number of defects each day (or each shift, preferably) in a c-control chart, which is a control chart for number of defects. After enough data (at least a month) have been collected, the organization should calculate the control limits. From that point, it can use the control chart to evaluate the process and determine when an assignable cause has been identified.

The control chart is a monitoring tool that can feed other statistical tools to improve processes. If control charts show that shift-to-shift variation is too high, for example, other tools can be used to determine the source of such variability, such as the F-test, Levene test or design of experiments. After the improvements are implemented, control charts can be used to track the improvement, as shown in Figure 2 (p. 21).

Final inspection: If all previous inspections (incoming and in-process) are well-executed, there should not be too many defects left from the process after it's completed. Figure 3 shows how defects should be funneled throughout the different inspection points. Still, a final inspection is necessary as a warranty that no defective product is released to the customer.

A common approach used by organizations at this stage is to implement the same acceptance sampling plans they used at incoming inspection: ANSI/ASQ Z1.4 or ANSI/ASQ Z1.9. However, as mentioned earlier, there is a big disadvantage to using this kind of approach: accepting a lot with one or more defects.

To avoid this situation, many organizations start tweaking the inspection plans to obtain a plan with acceptance of zero defective product and rejection of one or more defective products. Most of the time, they achieve that plan by selecting a lower AQL. Not only is this an incorrect application of

FIGURE 3

Approaches to monitor the process

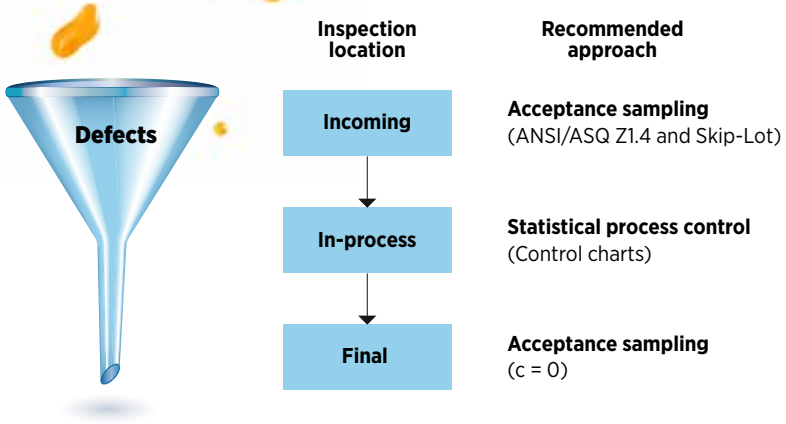


TABLE 1

Example of a sampling plan using ANSI/ASQ Z1.4 and c = 0

Lot size	12,000	12,000
Inspection level	II	N/A
AQL	0.65	0.65
Sample size	315	77
Accept (Ac)	5*	0
Reject (Re)	6*	1

** If an Ac = 0 and Re = 1 want to be obtained, an AQL of 0.040 would be required.*

the sampling plan, but the sampling sizes obtained by these plans also are unnecessarily high.

An alternative is to use the zero-acceptance (c = 0) sampling plan developed by Nicholas L. Squeglia. This plan is an adaptation of the acceptance sampling plans covered earlier (specifically, for the ANSI/ASQ Z1.4). In the zero-acceptance sampling plan, however, the probability of accepting a lot with a certain percentage of defective product or higher is very low. In this case, there is a safeguard to the customers that no defective product will be released.

This safeguard to the customer is not the only reason to use this type of plan at final inspection. Most of the time, the sample sizes calculated from the zero-acceptance sampling plans are much lower than those for the ANSI/ASQ Z1.4 and at the same AQL values. In other words, the sample sizes will be much lower, while keeping the same protection to the customer.

Table 1 shows an example of a sampling plan for a lot size of 12,000 parts and an AQL of 0.65. Using the ANSI/ASQ Z1.4, a total of 315 samples would have to be collected, whereas by using the c = 0 sampling plan, only 77 samples would have to be collected (a 76% reduction).

Not only is there a significant reduction in the sample size, but for the ANSI/ASQ Z1.4 plan, the lot could be accepted with five defective parts and rejected with six rejected parts. If zero defective parts is the only accepted level, the AQL must be reduced to 0.040. As noted earlier, reducing the AQL is not the right approach.

It is important to note another aspect of the c = 0 sampling plan: When one or more defective products are obtained using this plan, the lot is withheld. The phrase "withhold the lot" is significant because it does not necessarily mean rejection.

Under these plans, the inspector does not necessarily reject the lot if one or more defective products is found. The inspector only accepts the lot if zero defective product is found in the sample. Withholding the lot forces a review and disposition by engineering or management personnel to determine the extent and seriousness of the defective product.

Improving inspection activities

Sampling is an important consideration in most organizations, especially when the sampling is destructive in nature. Organizations spend huge amounts of resources (personnel and economic) during inspection activities. Often, even with many samples, defective product is released to the customer.

Sampling is an important consideration in most organizations, especially when the sampling is destructive in nature.

This is, in part, because the correct sampling approaches weren't implemented. By implementing the correct incoming, in-process and final inspection approaches, organizations can improve their inspection activities and provide a better product to their customers. QP

BIBLIOGRAPHY

Peña-Rodríguez, Manuel E., *Statistical Process Control for the FDA-Regulated Industry*, ASQ Quality Press, 2013.

Squeglia, Nicholas L., *Zero Acceptance Number Sampling Plans* fifth edition, ASQ Quality Press, 2008.

Taguchi, Genichi, Subir Chowdhury and Yuin Wu, *Taguchi's Quality Engineering Handbook,* John Wiley & Sons, 2005.

Manuel E. Peña-Rodríguez is a consultant at Business Excellence Consulting Inc. in Guaynabo, Puerto Rico. He earned a Juris Doctor from Pontifical Catholic University in Ponce, Puerto Rico, and a master's degree in engineering management from Cornell University in Ithaca, NY. Peña-Rodríguez is a senior member of ASQ and an ASQ-certified quality engineer, auditor, manager of quality/organizational excellence, Six Sigma Black Belt, biomedical auditor, and hazard analysis and critical control points auditor.

Just the Facts

Process validation is a tool used to ensure product safety and efficacy.

It is required by regulation bodies when a process can't be verified by inspections or tests.

It's important for manufacturers to understand process validation and the regulatory requirements so they can produce products that are safe for their intended use.

eking Validation

Practical process validation ensures products meet specifications | **by Bob Mehta**

Process validation is an important influencer in manufacturing, regardless of industry. In the biomedical industry, for example, it's imperative medical devices are safe and effective for their intended use.

One of the tools used to ensure product safety and efficacy is process validation. Regulators, such as the U.S. Food and Drug Administration (FDA), require process validation activities be pursued in all aspects of device manufacturing.

In fact, the need for process validation has been codified in the FDA's quality system regulation (QSR).[1] Failure to comply with device establishments and the QSR—including the requirements for process validation—could result in the FDA taking regulatory action, such as issuing a Form FDA 483—List of Inspectional Observations, which notifies an organization's management of objectionable conditions found during an inspection, or a warning letter.

Understanding the regulatory requirements, the perils associated with failing to meet process validation regulations and the fundamentals of practical process validation can ensure device manufacturers are producing safe and reliable products.[2]

Regulatory requirements

The QSR is specific: If a process cannot be verified through inspections and tests, the process must be validated. This is nonnegotiable with the FDA—failure to properly validate a process is considered a violation of the QSR. The FDA frequently cites these violations in Form 483 and warning letters.

The regulation identifies process validation as follows:

"(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

(b) Each manufacturer shall establish and maintain procedures for monitoring

and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented."[3]

FDA warning letter

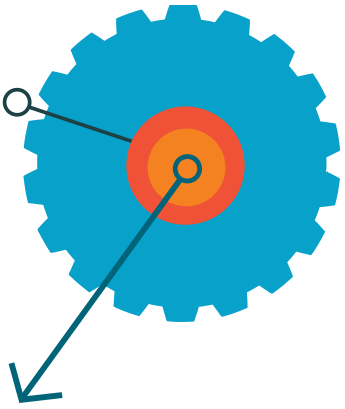
During an inspection, the FDA almost always assesses an organization's approach to process validation. In doing so, the agency reviews the organization's process validation records, including protocols, reports and deviations.

If the organization fails to establish a robust approach to process validation, the FDA will cite the violation in a manner similar to the following excerpt from a warning letter issued to BroadMaster Biotech Corp. (BMB) in 2016. (Note: The original letter has been generalized for clarity. Text redacted by the FDA is represented by "X.")

Dear Mr. X,

Failure to ensure that, when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 820.75(a). For example, the X describes the process used to manufacture the final X. However, BMB has not validated this X. Specifically:

+ When records were requested, such as protocols and test reports, that might support validation of the process described in X, you stated that BMB did not have these records. You stated that the procedure X serves to demonstrate that this X process is validated. However, the inspection procedure does not describe a full qualification of the X process.
+ X states that X's that pass this inspection may be stored for up to X. When asked how BMB verified that the X may be stored for X before use—and specifically whether X had a predefined method, acceptance criteria and statistically valid sampling plan—you stated that BMB did not have this type of information to support the storage of the X.
+ Additionally, the inspector requested information regarding the X steps described in X. BMB stated that these X steps were employed because the X and BMB want to remove potential bioburden and dust contamination. However, BMB stated that it had never analyzed the X.[4]



Practical process validation

When embarking on a practical approach to process validation, an organization must consider several elements, including:

+ Validation prerequisites.
+ Validation considerations.
+ Validation master plan.
+ Revalidation requirements.
+ Sample size.
+ Process monitoring.
+ Common validation issues.

One of the first questions an FDA investigator asks during an inspection is about the availability of the organization's process validation procedure. At a minimum, the organization should ensure that its scripted procedure touches on these elements.

Validation prerequisites

Validation prerequisites can be numerous, but the basics—such as calibration, environmental conditions, test method validation (TMV), training and the validation protocol—are important influencers to consider.

For starters, all measuring and monitoring equipment used to support process validation must be current in their calibration and preventive maintenance (PM) cycles. It is imperative for calibration to be performed by a qualified metrology service (ISO/IEC 17025 accredited) with traceability to national standards, such as those published by the National Institute of Standards and Technology.

Additionally, any potential influence that environmental conditions may have on the process to be validated must be understood. If

temperature, relative humidity or the need to manufacture in a controlled environment is critical to the process, these conditions must be called out in the validation protocol.

Furthermore, the test methods used to obtain process validation data also must be validated. The measurement modalities used must provide accurate and repeatable results. In some cases, a design of experiments may be necessary to support process validation.

Finally, training is critical. All employees participating in the process validation must be appropriately trained, and the training must be documented. Employees should be trained in the organization's high-level validation procedure and the validation protocol, which should be captured in the actual protocol.

One of the first questions an FDA investigator asks during an inspection is about the availability of the organization's process validation procedure.

Considerations

Risk is an important consideration when validating a process. There cannot be an intelligent discussion about the influence of risk until a process failure mode and effects analysis (pFMEA) is created.

Prior to undertaking process validation, the initial risk indexes gathered from the pFMEA can be used to determine the sample size requirements for each process to be validated. Additional process validation considerations are driven by the type of process validation pursued, such as:

+ Installation qualification (IQ).
+ Operational qualification (OQ).
+ Performance qualification (PQ).
+ Process performance qualification (PPQ).

IQ ensures that key aspects of the process equipment and ancillary system installations adhere to the manufacturer's specifications and that the equipment has been properly installed. Considerations for IQ should include, as applicable:

+ A description of equipment and design features.
+ Verification of correct startup sequence and setup parameters.
+ Verification of calibration, PM requirements and equipment cleaning schedules.
+ Verification of applicable drawings, manuals and associated documentation.
+ Verification that the required utilities are supplied (voltage and air pressure, for example).
+ Verification of functional sequences for machine operation (including safety features) and spare parts list.
+ Verification of environmental requirements.

OQ ensures that the equipment process control limits meet all predetermined requirements. During OQ, the process control limits are challenged to provide evidence that the predetermined process output requirements associated with the product meet the predetermined requirements.

For OQ, sample size selection is premised on the initial process risk index and data type (variable or attribute). Considerations for OQ related to equipment should include, as applicable:

+ Verification of controls and safety features.
+ Availability and accuracy of equipment operator manuals.
+ Accuracy and control of equipment throughout specified ranges.
+ Verification that the firmware and software perform as specified.
+ Definition of PM, cleaning and calibration requirements.

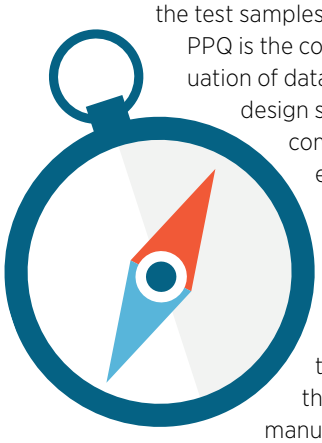
Considerations for OQ related to processes should include, as applicable:

+ Process control limits.
+ Sterilization effects.
+ Environmental conditions and impact.
+ Software and firmware parameters.
+ Material handling requirements.
+ Operator training.
+ Short-term process stability and capability studies.

PQ ensures that a process consistently produces a result or product that meets predetermined requirements (reproducible and repeatable). PQ testing should always take place at nominal process conditions using samples taken from product lots representative of production. Considerations associated with PQ should include, as applicable:

+ Environmental conditions.
+ Operators involved in product manufacturing.
+ Multiple material lots for the validation runs, if possible.
+ Sufficient characterization of the raw materials employed in the

qualification runs (including the qualification of suppliers).
+ Equipment setup while building the test samples and equipment.



PPQ is the collection and evaluation of data from the process design stage through commercialization. It ensures that a process is capable of consistently delivering quality products. The object of PPQ is to demonstrate that all validated manufacturing processes produce finished products that meet their specifications. PPQ looks at an entire manufacturing process, not just a single process. Complete product configurations are built in accordance with nominal process conditions.

In support of PPQ, samples should be taken from lots representative of production so that data generated in accordance with the PPQ protocol affirms that the entire manufacturing process being challenged reflects that all significant variables are in a state of control. Sample size selection is premised on the initial process risk index and data type.

Validation master plan

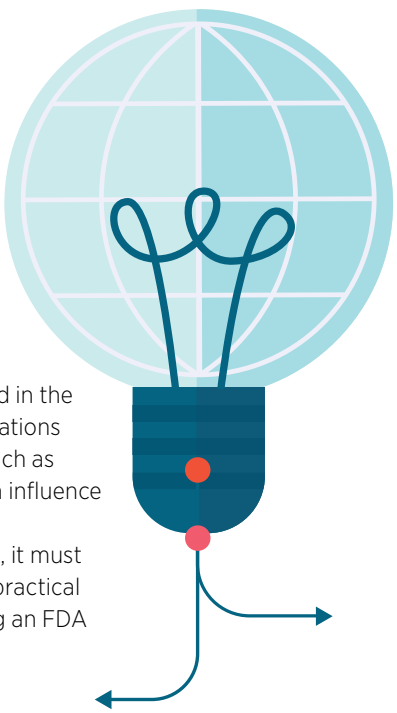
The validation master plan (VMP) serves as the validation roadmap. The main output of a VMP is a list of validated items and the associated documentation, including schedules for revalidation and retrospective validation activities.

The following elements should be considered for inclusion in the VMP:
+ Introduction—the validation strategy overview.
+ Organizational structure—the individuals responsible for determining validation needs, protocols, approvals and execution.
+ Plant, process and product descriptions—the rationale for inclusion or exclusion in the VMP.
+ Specific process considerations—all requirements.
+ Validated products, processes and systems—a list of all validation activities including utilities, processes and TMV, including processes that are not validated or supported by appropriate rationale.
+ Key acceptance criteria—the acceptance criteria for all validation activities.
+ Documentation format—the naming and numbering conventions used for validation protocols and reports.
+ Reference procedures—a list of standard operating procedures, work instructions, templates and forms used for process validation.
+ Plan and schedule—a schedule that delineates validation, revalidation and retrospective validation requirements.
+ Record and change control—requirements for good documentation practices and record storage, retention and approval.

Revalidation requirements

Process revalidation is driven by multiple factors, including:
+ New or relocated equipment.
+ Change in materials.
+ Process parameter changes.
+ Process stability concerns.
+ Procedural changes.
+ A predefined time interval.

Revalidation requires the re-execution of a validation protocol and is a widely accepted alternative to retrospective validation. The determination for revalidation activities should be delineated in the VMP, including the frequency of periodic reviews or conditions that require process revalidation.



Sample size considerations

It is imperative for the sample size and sample size rationale to be clearly defined in the validation protocol. Sample size considerations are driven by risk and defined in terms such as reliability and confidence intervals, which influence sample size.

Regardless of the sample size selected, it must be robust, adequate enough to support practical process validation and defendable during an FDA inspection.

Process monitoring

Process monitoring is performed through the application of statistical process control (SPC) techniques. SPC

uses control charts to gauge the ongoing performance of a process. Control charts provide information for timely decisions concerning the process and quality of the products produced by the process.

Control charts also are problem-solving tools used to investigate the causes of poor product quality and are essential for continuous monitoring of validated processes. Control chart data are useful when performing revalidation or retrospective validation activities.

Organizations often find these types of control charts useful:

+ X-bar and R charts.
+ C-charts.
+ µ-charts.
+ np-charts.
+ P-charts.

Common validation issues

When pursuing an approach to practical process validation, organizations should be cognizant of the common pitfalls. Some of the issues that quickly become problematic if they aren't considered or addressed properly are:

+ Improper line clearance practices.
+ Improperly documented or undocumented deviations in the process validation protocol.
+ Undocumented sample size and selection rationale.
+ Insufficient samples.
+ Improperly identified materials used, including lot and batch numbers.
+ Improper or no training.
+ Undefined revalidation criteria.
+ Uncalibrated measuring and monitoring equipment.
+ An unassessed measurement system.
+ Identical pieces of equipment and tooling that aren't validated.
+ Not obtaining document approvals (reports and protocols).
+ Not using a VMP as a road map for validation activities.

Stay on good terms

Any organization can achieve practical process validation. Because process validation is a regulatory requirement mandated by the FDA when the results of a process cannot be fully verified by subsequent inspections or tests, process validation isn't optional—it's mandatory. However, process validation activities are scalable depending on the size, products, risk and process complexity of the organization.

When properly implemented, practical process validation can result in manufactured devices that are reliable, safe and effective for their intended use. Additionally, properly documented validation activities (protocols and reports) will keep organizations in the good graces of the FDA.

Not properly validating processes or taking shortcuts in the interest of saving money doesn't end well for organizations. Pursuing practical process validation, however, will always result in cost savings and better product quality. QP

Regardless of the sample size selected, it must be robust, adequate enough to support practical process validation and defendable during an FDA inspection.

REFERENCES AND NOTE

1. U.S. Food and Drug Administration (FDA), Code of Federal Regulations Title 21, Section 820.75—Process validation, revised April 1, 2017, https://tinyurl.com/y8lj3dbc.
2. For more information about process validation, read Mark Allen Durivage and Bob Mehta, *Practical Process Validation*, ASQ Quality Press, 2016.
3. FDA, Code of Federal Regulations, see reference 1.
4. "BroadMaster Biotech Corp. 10/4/16," FDA, https://tinyurl.com/y7ggnthb.

Bob Mehta is a principal consultant at GMP ISO Expert Services in Mission Viejo, CA, for the FDA-regulated industry. He earned a master's degree from California State University, Dominguez Hills, in Carson and an MBA from Pepperdine University in Malibu, CA. Mehta is an ASQ fellow, recipient of the ASQ Los Angeles Section's Simon Collier Quality Award, co-author of Practical *Process Validation* (ASQ Quality Press, 2016) and author of *Implementing ISO/IEC 17025:2005: A Practical Guide* (ASQ Quality Press, 2013). He is an ASQ-certified hazard analysis and critical control points auditor, quality manager, software engineer, biomedical auditor, reliability engineer, auditor, engineer and Six Sigma Black Belt.

When FAILURE to COMPLY is Not an Option

Process decision program charts help manage compliance rule changes for safety of underground natural gas storage | **by James L. Gooding**

Managing change can demand more from an organization than the usual thoughts about migrating to new cultural values, behaviors and practices. Organizations whose activities are regulated by government authorities sometimes find that compliance rules can change quickly, and adjusting to rule changes cannot be contested, postponed or negotiated. Falling out of compliance at any level—especially when operating licenses or permits are at stake—could easily mean costly interruption of business, if not loss of the business altogether.

All regulations, and the compliance rules they promulgate, are subject to change—especially after high-profile incidents or shifts in political sentiment. Recognition and accommodation of uncertainties surrounding changes in compliance rules should be integrated into the enterprise risk management (ERM) plan, which is meant to protect or mitigate against all operational, financial and reputational risks.

Just the Facts

Business operations contingent on regulatory compliance must be able to swiftly adjust to rule changes after major incidents.

A process decision program chart (PDPC) can show risks and countermeasures, helping executives and technical specialists see the big picture when regulatory compliance rules change.

New operational integrity rules for U.S. underground natural gas storage facilities offer an example of how the PDPC approach can benefit compliance planning.

Change management for compliance

When compliance rules change, the risks that can emerge for the enterprise relate to three key rule change attributes:

1. **Expanded scope.** This means that new rules are made or existing rules are applied to a larger breadth or depth of enterprise activities. Compliance planning should include an assessment of whether the expanded rules are based on new laws or a reinterpretation of existing laws because the legal ramifications may differ for those two possibilities.
2. **Redefined jurisdiction.** This means that the identity changes for the primary regulatory administrator of the rules and, therefore, the authority to whom the enterprise must report. Examples could be the appearance of a new regulatory agency or an event in which one regulatory agency supplants another. In either case, a change of jurisdiction inevitably introduces new uncertainties in how best to meet the new regulator's expectations.
3. **Elevated hurdles.** Even if rules are not expanded and regulatory jurisdiction is left unchanged, elevated hurdles could mean that a higher standard for compliance is applied to an existing regulatory framework. Examples could be intensified levels of inspections or audits, or more frequent compliance reports.

FIGURE 1

Process decision program chart framework for compliance changes

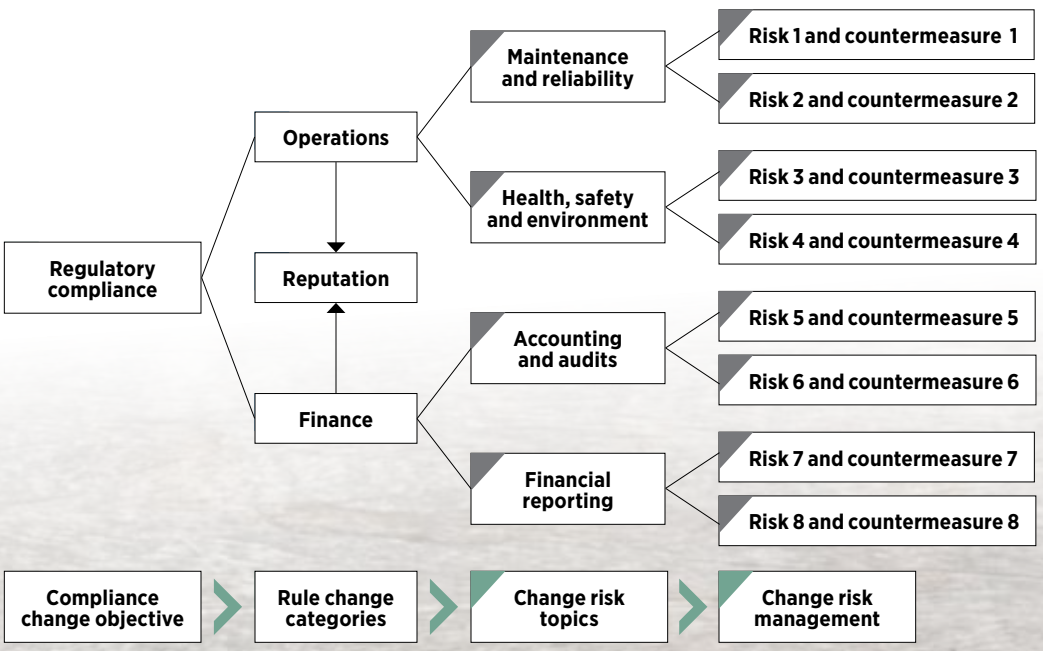


TABLE 1

Rule change compliance matrix for PDPC

Rule change category	Change risk topic	Change management action	
		Compliance risk	Rule change attribute* and countermeasure
Operations	Maintenance and reliability	System and process validation	ES: Third-party validation of design and operating procedures RJ: Revise procedures and documentation to align with new authority EH: Raise priority and resource allocations for compliance in ERM plan
		Equipment testing and certification	Patterned after above
		Personnel training and certification	Patterned after above
	Health, safety and environment	Process safety	ES: Third-party verification of alignment with industry standards or best practices RJ: Implement inspections and certifications to align with new authority EH: Raise priority and resource allocations for compliance in ERM plan
		Personnel safety	Patterned after above
		Environmental nondegradation	Patterned after above
Finance	Accounting and audits	Accounting method validation	ES: Third-party verification of alignment with industry standards or best practices RJ: Revise audit processes and certifications to align with new authority EH: Raise priority and resource allocations for corporate governance
		Audit integrity	Patterned after above
		Personnel training and certification	Patterned after above
	Financial reporting	Statement of assets and liabilities	ES: Verification by independent, third-party auditor RJ: Revise reporting standards to align with new authority EH: Raise priority and resource allocations for corporate governance
		Statements of cash flow, revenue and earnings	Patterned after above
Reputation	Impact from operations	Operational incident creates bad image	Evaluate new risks from ES, RJ or EH changes in operations
	Impact from finance	Accounting or audit incident creates bad image	Evaluate new risks from ES, RJ or EH changes in finance

Rule change attributes:* ***ES* *= expanded scope* ***EH*** *= elevated hurdles* ***RJ*** *= redefined jurisdiction* ***PDPC*** *= process decision program chart*

The ERM plan should include one or more tools that directly address compliance risks along with regular management reviews to ensure that compliance planning is updated and working as intended. Several quality tools could be useful in addressing compliance risk planning, including those used frequently in failure mode and effects analysis.

Nonetheless, perhaps the single best starting point is the process decision program chart (PDPC), which is a time-tested technique for mapping risks and potential countermeasures to clarify relationships, contingencies and consequences.[1]

PDPC basics for compliance planning

A PDPC represents a specific objective laid out as a tree diagram in which the individual steps needed to accomplish the objective grow branches according to alternative, intermediate outcomes (decision points) that present options for prospective next steps.

Successively finer branches denote risk management actions that could be taken in response to a particular risk, such as outsourced rather than in-house inspections, or online rather than instructor-led training. The complete picture should serve as a master overview of how to recognize and overcome risks in achieving the stated objective.

Figure 1 shows a high-level PDPC for the general case of planning for regulatory compliance. The objective is to achieve and maintain compliance with one or more regulatory rules that are subject to change.

Among the three top-level risk categories, operations and finance are treated individually because they typically are direct regulatory targets governed by compliance rules issued by different authorities. Reputation—as the third major risk category—is not a direct regulatory target, although it usually is affected significantly by compliance successes or failures in operations and finance.

Table 1 (p. 33) provides a more detailed template for how compliance risks can be organized into a PDPC-compatible body of relationships. The three left-most columns in Table 1 span the categories, topics and top-level risks that are common to regulatory change management in all enterprises.

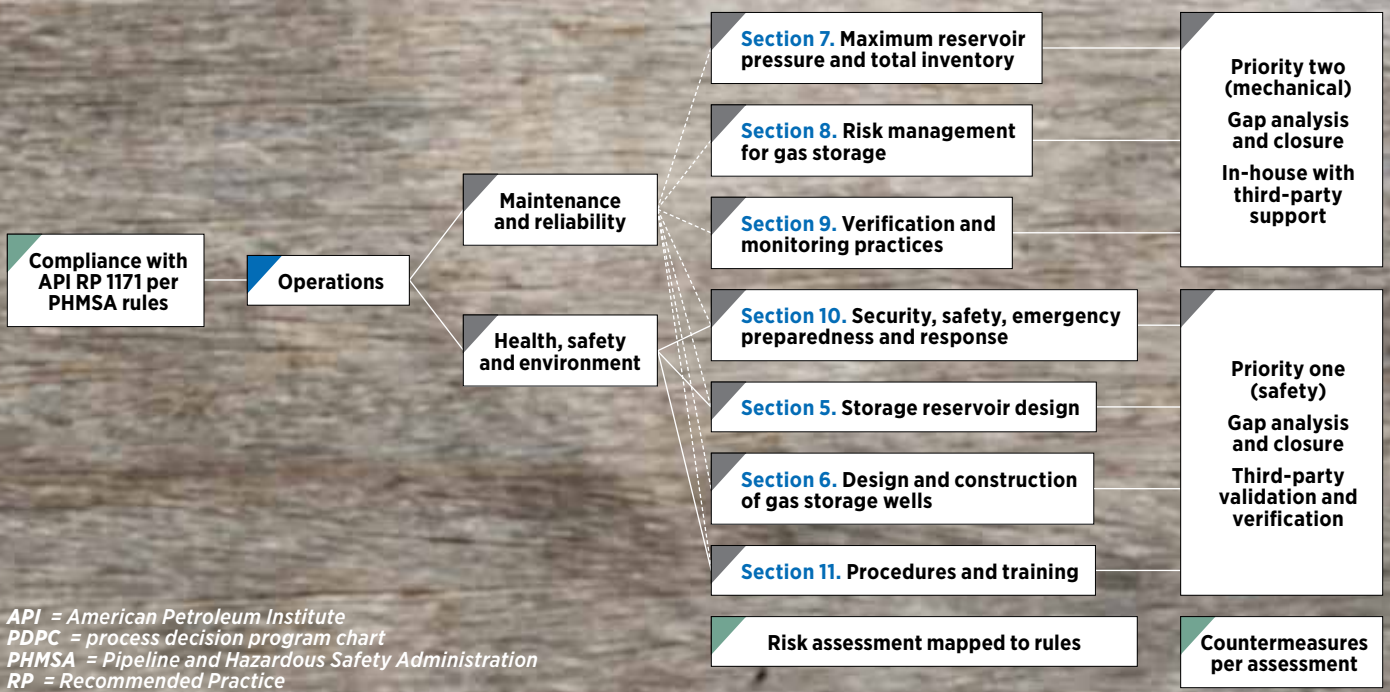
For application to a specific enterprise, however, the "rule change attribute and countermeasure" column must be populated with content that is relevant to specific rule changes faced by that enterprise. The latter requires input from enterprise experts, as well as proficiency in PDPC development and use. In practice, there might be multiple countermeasures available for each rule change attribute.

The template in Table 1 is meant to drive the assessment process to ensure there is at least one countermeasure for each identified risk.

Deliberately absent from the templates in Figure 1 and Table 1 is any attempt to rank risks by likelihood or consequence, which is commonly done in some other risk management tools, such as decision matrixes, strength-weakness-opportunity-threat dashboards or Monte Carlo simulations. Setting likelihood aside in this application is appropriate because any failure to comply with regulatory rules almost always is a high-consequence event. The ERM plan should

FIGURE 2

PDPC for gas storage facility compliance with API RP 1171



API = American Petroleum Institute
PDPC = process decision program chart
PHMSA = Pipeline and Hazardous Safety Administration
RP = Recommended Practice

An independent assessment of technical operating procedures by a respected industry expert can be a powerful element of a successful report or permit application with a regulator.

treat any prospective compliance risk as a high priority—regardless of perceived probability.

References in Table 1 to third-party involvement in the compliance risk mitigations are meant to remind you that risk management often is well served by diversifying the effort to include opinions of independent experts as testimony in regulatory filings and reports. A respected third-party evaluator or auditor can bolster the case for compliance in ways that in-house experts alone could not.

Perhaps the most familiar example is in finance, in which the use of external auditors (in addition to internal auditors) is usually essential for compliance to accounting standards.

The value proposition for external auditors, however, can be equally strong for compliance in operations. An independent assessment of technical operating procedures by a respected industry expert can be a powerful element of a successful report or permit application with a regulator.

Example: New compliance rules for the U.S. natural gas industry

Substantial regulatory changes in 2016 and 2017 affected the compliance requirements for the operation of underground natural gas storage facilities in the United States. As of this publication date, facility responses to the new compliance requirements are in their first reporting cycle, thereby providing a business-relevant opportunity for applying the PDPC approach to managing compliance risks.

Underground storage of natural gas in repurposed geologic reservoirs has been an essential part of energy infrastructure in the United States since 1916 and, as of the end of 2017, more than 400 individual facilities together accounted for greater than 8 trillion cubic feet of gas in storage.[2]

The large majority of the storage facilities have operated without incident for many decades, with most facilities under the regulatory purview of the states in which they are located. However, a large and prolonged gas leak from the Aliso Canyon, CA, facility from October 2015 to February 2016 displaced thousands of nearby residents from their homes and brought intense public, political and regulatory scrutiny to the gas storage industry.[3]

The Aliso Canyon leak led to a new U.S. federal law, the Protecting Our Infrastructure of Pipelines and Enhancing Safety (PIPES) Act of 2016, which required the first-ever nationwide operating rules, beginning in 2017 and 2018, for all gas storage facilities regardless of their state regulatory purviews.[4]

The new compliance requirements can be called the PHMSA Rules, named after the U.S. Pipeline and Hazardous Materials Safety Administration (PHMSA) that issued the rules under its statutory

responsibility and authority in December 2016.[5] Although the PHMSA Rules pertain to all types of storage reservoirs, the technical standards differ in detail for depleted petroleum reservoirs (which are treated together with aquifer reservoirs) compared with salt cavern reservoirs.[6]

PDPC application to gas storage operations compliance

Figure 2 (p. 34) illustrates a PDPC approach that would be suitable for underground natural gas storage facilities of the Aliso Canyon type (a depleted petroleum reservoir) to plan for compliance with the PHMSA Rules. Although the PHMSA Rules prescribe new annual fees to be paid by storage facility operators, the rules target operations rather than finance. Accordingly, the example presented here is for operations compliance only.

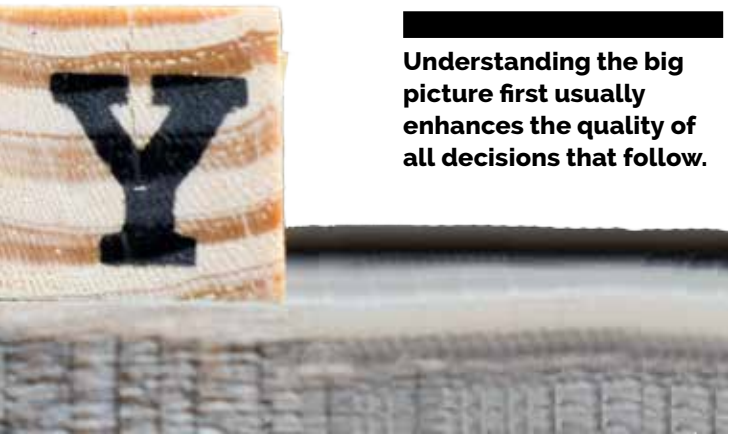
The PHMSA Rules adopt by reference—and prescribe as mandatory technical standards—two recommended practices (RP) published by the American Petroleum Institute (API). By combining new statutory authority with extensive technical requirements, the PHMSA Rules carry the three major rule change attributes:

1. Expanded scope is created because new federal rules address underground infrastructure (reservoirs and wells), whereas earlier federal rules dealt with only above-ground pipelines.
2. Redefined jurisdiction applies because PHMSA, a federal agency, becomes the primary administrator of the new rules, although the intent is for state regulators to become qualified as administrators over time.
3. Elevated hurdles are conspicuous because several new types of reports are required from storage operators annually and in the event of any operating incident.

In this example, the relevant standard is API RP 1171,[7] which organizes guidance for depleted-reservoir storage facilities into seven major sections as parts five to 11. As shown in Figure 2, an operations risk assessment mapped onto the major sections of API RP 1171 reveals that mechanically focused requirements occur in all seven parts, while specific, safety-focused requirements occur in parts five, six, 10 and 11.

Because the emphasis of the PHMSA Rules is to demonstrate safe operations, any need to prioritize compliance responses should be expected to make safety-related compliance as priority one and mechanical compliance as priority two.

For priority one and two countermeasures, the first step would be to conduct a gap analysis to identify any nonconformities between current facility practices and the requirements prescribed by the



Understanding the big picture first usually enhances the quality of all decisions that follow.

PHMSA Rules. Gap recognition would occur through a process audit to identify provisions of prescribed rules that are not positively documented in current operational records.

Depending on the size of the enterprise, closing the gaps through updated processes and procedures might be accomplished in-house or with support from third-party experts. In the case of priority one countermeasures, third-party participation could be valuable in preparing compliance filings with PHMSA that independently demonstrate consistency with best practices recognized by PHMSA for other industry participants.

Clearly, Figure 2 cannot realistically depict every level of detail required for a comprehensive assessment of compliance risks and countermeasures relative to all 52 pages of API RP 1171. The discussion presented here, however, should provide a pathway for using the PDPC approach to develop a thorough map of prioritized risks and countermeasures.

Recommendations for PDPC-based compliance planning

Planning for effective regulatory compliance should not be limited to any single risk management tool. However, the PDPC offers a useful starting point that has the advantage of a graphical depiction of risks and countermeasures, which can help executives and technical specialists see the big picture. Understanding the big picture first usually enhances the quality of all decisions that follow.

An enterprise with an ERM plan should naturally have quality managers onboard who can guide the development and use of PDPC maps for compliance planning. If not, the enterprise probably will want to call on outside services to provide the needed support. In all cases, careful consideration should be given to how, where and when third-party experts should be used to bolster the case for compliance with regulatory authorities. QP

REFERENCES

1. John E. Bauer, Grace L. Duffy and Russ T. Westcott, eds., *The Quality Improvement Handbook,* second edition, ASQ Quality Press, 2006, pp. 137-138.
2. U.S. Department of Energy Information Administration, "The Basics of Underground Natural Gas Storage," Nov. 16, 2015, www.eia.gov/naturalgas/storage/basics.
3. Governor's Office of Emergency Services, State of California, "Aliso Canyon Natural Gas Leak," www.caloes.ca.gov/ICESite/Pages/Aliso-Canyon.aspx
4. "Pipeline Safety: Safety of Underground Natural Gas Storage Facilities," 49 CFR Parts 191 and 192, Pipeline and Hazardous Materials Safety Administration (PHMSA), Federal Register, Vol. 81, No. 243, Dec. 19, 2016, pp. 91,860-91,873 www.gpo.gov/fdsys/pkg/FR-2016-12-19/pdf/2016-30045.pdf.
5. Ibid.
6. U.S. Department of Energy Information Administration, "The Basics of Underground Natural Gas Storage," see reference 2.
7. American Petroleum Institute (API), API Recommended Practice 1171—Functional Integrity of Natural Gas Storage in Depleted Hydrocarbon Reservoirs and Aquifer Reservoirs, Sept. 1, 2015, p. 52, www.techstreet.com/api/standards/api-rp-1171?product_id=1902237.

James L. Gooding is managing director of Geoclime LLC in Seabrook, TX. He earned a doctorate in geology from the University of New Mexico in Albuquerque and has worked in the natural gas industry. He is a senior member of ASQ and an ASQ-certified manager of quality/organizational excellence.

Becoming A Master

Do you have what it takes to achieve mastery? | **by David Kachoui**

Every quality manager wants to build a team of avid learners who continually improve. To do that, the quality manager must first build his or her own competency in the quality field to develop personal mastery. The quality manager also must hone his or her teaching and coaching skills while leading his or her team and develop the team's quality skills.

This creates a quandary because the quality manager's success in developing his or her team's quality skills is not something the quality manager can directly control. After all, learning is not something done to the learner, but something the learner does. So how can the quality manager ensure his or her team puts forth the necessary effort to learn the right things? The answer lies in mastering the skillset of management.

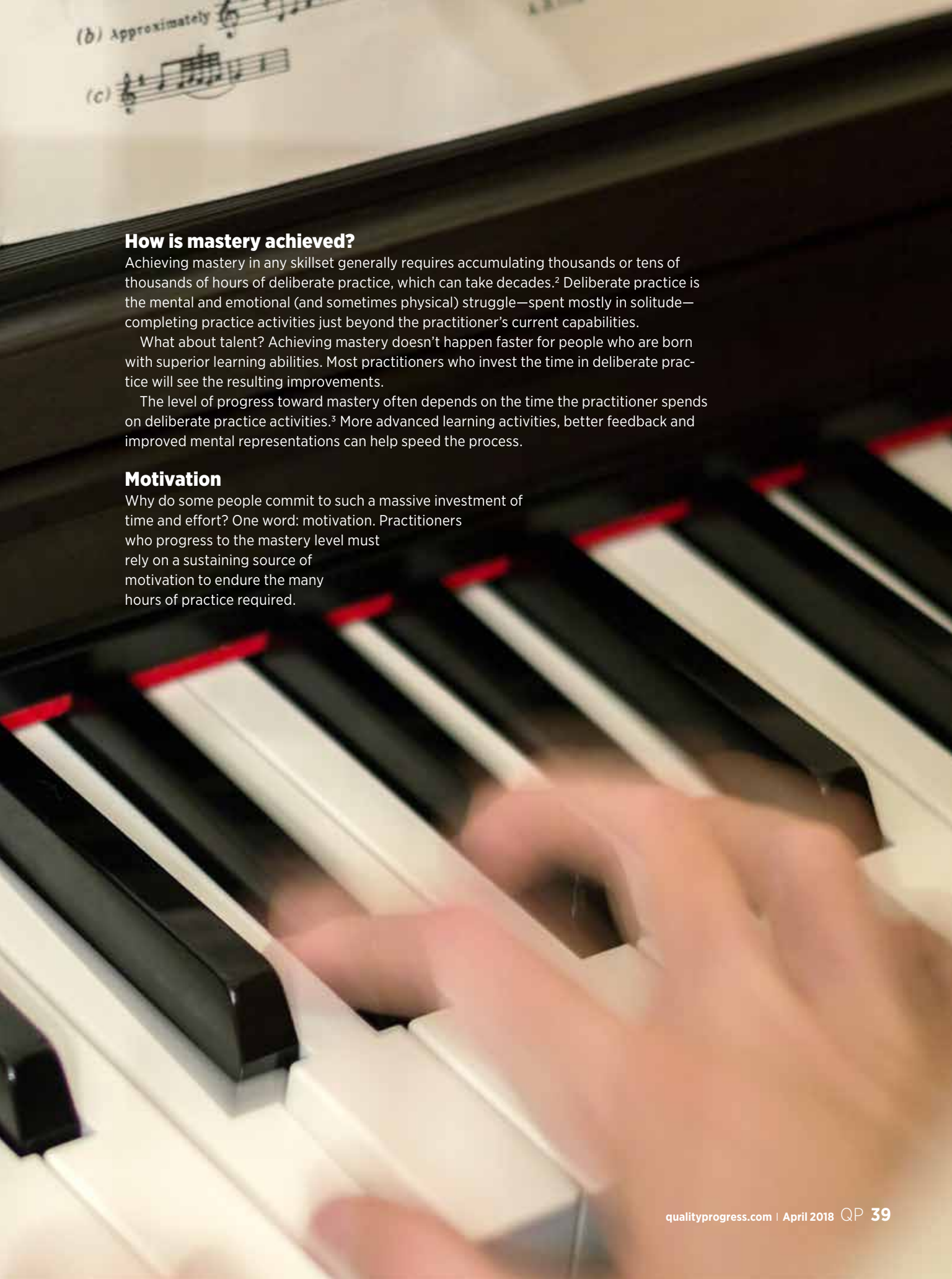
Management is a practice, which means mastering it requires developing skills through on-the-job experience. To develop his or her team's skills, the quality manager must master the key skills of designing and implementing learning programs.[1]

Just the Facts

To achieve mastery in any skillset, thousands of hours must be spent deliberately practicing.

People who achieve mastery are driven primarily by the reward of the activity itself, known as intrinsic motivation.

The four sources of intrinsic motivation are connection, contribution, gratification and relatedness.



How is mastery achieved?

Achieving mastery in any skillset generally requires accumulating thousands or tens of thousands of hours of deliberate practice, which can take decades.[2] Deliberate practice is the mental and emotional (and sometimes physical) struggle—spent mostly in solitude—completing practice activities just beyond the practitioner's current capabilities.

What about talent? Achieving mastery doesn't happen faster for people who are born with superior learning abilities. Most practitioners who invest the time in deliberate practice will see the resulting improvements.

The level of progress toward mastery often depends on the time the practitioner spends on deliberate practice activities.[3] More advanced learning activities, better feedback and improved mental representations can help speed the process.

Motivation

Why do some people commit to such a massive investment of time and effort? One word: motivation. Practitioners who progress to the mastery level must rely on a sustaining source of motivation to endure the many hours of practice required.

Simplified views of motivation, such as pursuing pleasure and fleeing pain, do not explain more complex human behaviors, such as when people intentionally increase their discomfort and forego pleasure for a long time to achieve mastery.

Motivation generally can be classified into two types: extrinsic and intrinsic (see Table 1). Extrinsic motivation is driven by external rewards and consequences, such as carrots and sticks, while intrinsic motivation is driven by a person's internal urges in the absence of, or despite, external rewards or consequences. Extrinsic motivation is the stimulation of behavior that leads to separable outcomes while intrinsic motivation drives behavior because the activity itself is the reward.[4]

Whether motivation is intrinsic or extrinsic depends on its relationship to the person. For example, money is a common extrinsic motivator, but well-known businessman Warren Buffet described it as an intrinsic motivator when he said, "It's not that I want money. It's the fun of making it and watching it grow."[5] For him, the activity served as its own reward.

Nurturing intrinsic motivation is a skill in and of itself. W. Edwards Deming identified nurturing intrinsic motivation as a key management responsibility.[6] In addition, intrinsic motivation is a better predictor of school, work and physical performance than extrinsic motivation.[7]

From the quality manager's perspective, developing his or her team's intrinsic motivation to achieve mastery in statistics, quality engineering or quality auditing, for example, begins with the quality manager's understanding of the team's sources of intrinsic motivation.

Sources of intrinsic motivation

Many people have studied why people do what they do. In their article "Intrinsic and Extrinsic Motivations: Classic Definitions and New Directions," researchers Richard M. Ryan and Edward L. Deci identified autonomy, competence and relatedness as intrinsic motivational factors.[8]

Author Daniel H. Pink built on this idea and categorized intrinsic motivation into autonomy, mastery and purpose.[9] Many of the experiments supporting these categories looked only at the effects of autonomy on someone's intrinsic motivation to perform a simple task, such as solving an interesting puzzle for a few minutes.

But if not all intrinsic motivation is the same, being intrinsically motivated to spend a few minutes solving a puzzle is different from someone being intrinsically motivated to devote decades of his or her life to achieving mastery.

This provides useful insights but doesn't answer the key management question: Why do people choose one path over another when investing their time, effort and resources to achieve mastery? How can this insight improve the management techniques used to increase the likelihood of someone achieving mastery?

Looking at the qualities that make humans unique in the animal world gives insight into sources of intrinsic motivation. Seeking pleasure and avoiding pain exists in animals as a survival instinct, and mammals have further developed social desires and abilities. Humans have the unique ability and drive to:

1. Link their minds with others to form networks of collective wisdom where the quality of group decisions exceeds what they are able to achieve with individual decisions alone.
2. Share their memories, insights and foresights to consciously improve themselves and others.
3. Override their immediate urges to pursue remote rewards.[10]

These can be described as intrinsic motivation driven by connection, contribution and gratification (see Table 2).

Connection

Connection is the desire to belong, be accepted, be in the know, understand, share and hear stories, live vicariously through heroes and grow closer through common enemies. Ryan and Deci proposed relatedness as a separate source of intrinsic motivation and described it as belongingness and connectedness with a sense of being respected.[11]

In their book *Why We Do What We Do: Understanding Self-Motivation*, Deci and Richard Flaste cautioned against autonomy with isolation or alienation over connectedness and relatedness.[12] Humans use their unique capacity for mindreading—knowing what others

TABLE 1

Types of motivation

	Extrinsic motivation	Intrinsic motivation
Definition	**Driven by external rewards and consequences.**	**Driven by the reward of the activity itself.**

think, believe, desire, feel or know through predictive or reactive mental tools such as empathy—to support the social connection motivation.[13]

A quality manager could require his or her team members to improve their personal mastery in a particular area to achieve some higher purpose, give them full autonomy to implement and disappear until the tasks are completed. Even though this would be highly autonomous, the likelihood of these actions fully motivating a team is low because it would create disconnection. Instead, the quality manager would be better served by establishing regular and genuine personal connections with the team.

Contribution

Defining purpose as an intrinsic motivator also runs the risk of misinterpretation and opens the door to disconnection. In practice, the quality manager could associate objective with purpose and assume decreeing an objective would motivate his or her team.

David Packard, co-founder of Hewlett-Packard, described management by objective (MBO) as "a system in which overall objectives are clearly stated and agreed upon, and which gives people the flexibility to work toward those goals in ways they determine best for their own areas of responsibility."[14]

According to Deming, the problem with MBO is "that the performance appraisal or merit rating focuses on the end product, not on leadership to help people." He suggested it be called "management by fear."[15]

Purpose has been variously defined as "making an impact on the world beyond the self,"[16] contributing to something great and enduring[17] and "the intention to contribute to the well-being of others."[18] If the underlying intrinsic motivator is contribution to a purpose, this is better explained and captured by the term "contribution" than the term "purpose."

Why do people choose one path over another when investing their time, effort and resources to achieve mastery?

Contribution describes the sense of being needed and providing meaningful help and support to others. The intrinsic motivation to contribute can fuel the internal drive over the long term to continue improving and achieving higher levels of mastery in ways that matter.

Someone could perform the same acts of contribution to others but be driven by extrinsic motivation, such as the desire to receive praise or reward. For the very same acts of contribution, being motivated by the act of improving the outcomes of others qualifies as intrinsic motivation.

As an intrinsic motivator, contribution manifests itself through the combination of two emotions: pride and happy-for emotions.

In their book *The Cognitive Structure of Emotions*, Andrew Ortony, Gerald L. Clore and Allan Collins define pride emotions as those resulting from "the approval of one's own praiseworthy action" and happy-for emotions as "being pleased about an event presumed to be desirable for someone else."[19]

More praiseworthiness and unexpectedness increase pride emotions. Doing more presumably desirable things for people who are deserving and well-liked yields higher happy-for emotions.

On a practical level, the quality

TABLE 2

Intrinsic motivators

	Connection	Contribution	Gratification
Definition	**Closeness, belonging.**	**Being needed and meeting the need.**	**Achievement.**
Associated emotion or feeling	**Social bonding, togetherness.**	**Pride, happy for others.**	**Sense of accomplishment.**
Actions	**Accepting/excluding, us vs. them tribalism, groupthink, modeling behaviors.**	**Supporting others in meaningful ways.**	**Overcoming challenges.**

manager promotes higher levels of intrinsic motivation by telling a team member where his or her contribution is needed and how it is impactful, and supporting that ability to contribute rather than merely stating the team member's purpose, objective or result.

Framing a task as a genuine contribution better nurtures the source of intrinsic motivation and acknowledges the value of the individual.

The quality manager also should be aware that if a team member is the best in an area of meaningful contribution and suddenly is surrounded by others who are better, the team member's sense of contribution will decrease. In that case, he or she would want to find a different way to contribute or rely on another source of intrinsic motivation to continue improving.

Gratification

The promise of future mastery taps into the human ability to imagine what has not been experienced and override immediate urges to pursue distant rewards. Mastery has been defined as the desire to get better at something that matters[20] and the sensation of "a greater command of reality, other people, and ourselves."[21]

Author Robert W. White identified competence as a key motivational driver and defined it as a person's capacity to effectively interact with his or her environment.[22] Deci and Flaste elaborated on competence as an intrinsic motivator by including the level of challenge required to bring a sense of accomplishment.[23]

The challenge qualifier provides greater insight into the true source of intrinsic motivation. Ortony, Clore and Collins defined the compound emotion of gratification as "approving of one's own praiseworthy action and being pleased about the related desirable event." Praiseworthiness, unexpectedness and desirability all affect the intensity of gratification.[24]

People have sailed across oceans, climbed mountains and trekked to the poles driven, in part, by the challenges and misery encountered along the way. Surviving higher levels of danger can increase a person's sense of accomplishment after the task is completed. Standing on top of Mount Everest, for example, feels much better after overcoming the trials and tribulations along the way than if you landed in the same spot by helicopter.

The fact that the journey wasn't necessarily enjoyable can seemingly disqualify gratification as intrinsic motivation because the actual time spent preparing for and en route to the destination wasn't done because the tasks were enjoyable themselves, but for some future reward.

This reward is intrinsic, however, because the high levels of effort and pain, and low likelihood of success, contribute to enjoying the moments of success after they are achieved. This delayed gratification and promise of future gratification can sustain the practitioner through unenjoyable periods as he or she moves toward success. He or she may achieve mastery or progress toward mastery driven by the external achievements along the way, but the actual source of intrinsic motivation is the promise of emotional gratification, which is internal.

Managing for intrinsic motivation

Managing intrinsic motivation is a skill. And, as with any skill, the quality manager must invest time and effort to practice, reflect and make improvements to, over the course of decades, achieve mastery.

This starts with the quality manager increasing his or her awareness of and nurturing his or her own intrinsic motivation. By understanding the nature of connection, contribution and gratification as the sources of his or her own intrinsic motivation, the quality manager is better equipped to nurture the internal drive of his or her team to learn and improve, and eventually achieve mastery.

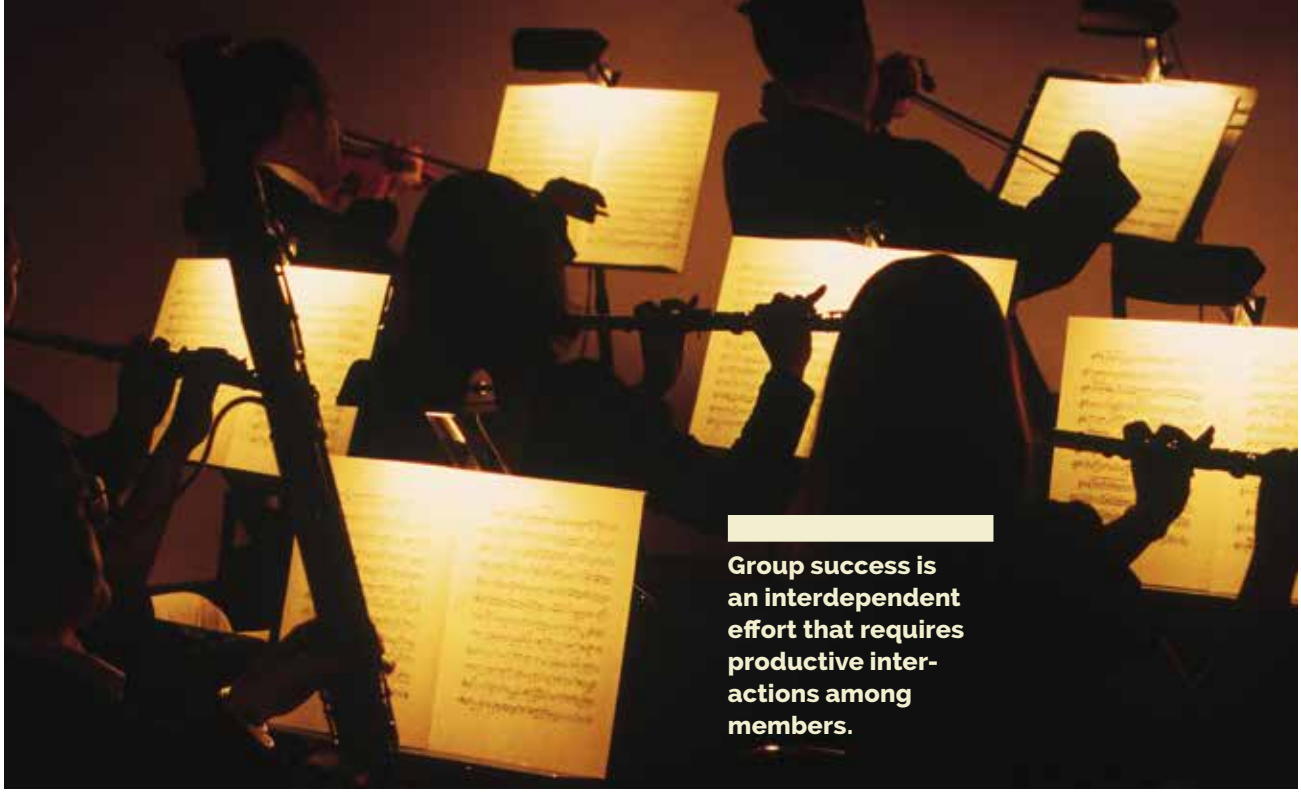
Being knowledgeable of intrinsic motivation helps the quality manager avoid the common pitfalls of inadvertently destroying it. Encouraging internal competition or reducing the time spent building productive relationships can decrease the sense of connectedness with others.

Replacing a team member's area of unique contribution with alternative options could come at the expense of the member's intrinsic motivation. Implementing extrinsic rewards for activities for which team members already enjoy the promise of gratification could distract from and potentially replace the underlying intrinsic motivation.

Group success is an interdependent effort that requires productive interactions among members. Juggling the complex and dynamic realities of groups complicates the quality manager's job. The quality manager must facilitate productive connections among team members and establish a personal connection with them so the quality manager is aware of individual members' intrinsic motivation levels.

As situations change and contributors come and go from the team, the quality manager must be aware of the effect on the other team members. Do they make productive connections with each other? Do they see the effect of their contributions decrease because other contributors are added and thus they lose their intrinsic motivation to contribute? Has the team lost sight of the fruits of its labor?

Being aware of this possibility and looking for early warning signs of compromised intrinsic motivation will help the quality manager identify and deal with the issues before they get worse. This also should help the quality manager empathize with team members.



Group success is an interdependent effort that requires productive interactions among members.

When mistakes happen, rather than blaming the team member for not caring or lacking intelligence or effort, the quality manager can move beyond pointing fingers to increasing intrinsic motivation by handling the situation in a supportive and respectful way. This ultimately leads to improved team development and organizational learning.

Of all of the skills a quality manager must master, managing for intrinsic motivation should be near the top of the list. By supporting deeper connections, acknowledging team contributions and enhancing gratification, the quality manager can increase his or her team's intrinsic motivation to master the skills it needs to succeed.

The design and implementation of his or her team's learning programs depend on the quality manager nurturing the team's intrinsic motivation. Only an intrinsically motivated learner will make the personal sacrifices required to engage in repetitive, solitary practice to reach mastery. QP

REFERENCES

1. Henry Mintzberg, *Managing*, Berrett-Koehler Publishers, 2009.
2. Anders Ericsson and Robert Pool, *Peak: Secrets From the New Science of Expertise*, Houghton Mifflin Harcourt, 2016.
3. Ibid.
4. Edward L. Deci and Richard M. Ryan, *Intrinsic Motivation and Self-Determination in Human Behavior*, Plenum Press, 1985.
5. Roger Lowenstein, *Buffett: The Making of an American Capitalist*, Random House, 2008.
6. W. Edwards Deming, *The New Economics*, Massachusetts Institute of Technology (MIT) Press, 1994.
7. Christopher P. Cerasoli, Jessica M. Nicklin and Michael T. Ford, "Intrinsic Motivation and Extrinsic Incentives Jointly Predict Performance: A 40-Year Meta-Analysis," *Psychological Bulletin*, Vol. 140, No. 4, 2014, pp. 980-1008.
8. Richard M. Ryan and Edward L. Deci, "Intrinsic and Extrinsic Motivations: Classic Definitions and New Directions," *Contemporary Educational Psychology*, Vol. 25, No. 1, 2000, pp. 54-67.
9. Daniel H. Pink, *Drive: The Surprising Truth About What Motivates Us*, Riverhead Books, 2009.
10. Thomas Suddendorf, *The Gap: The Science of What Separates Us From Other Animals*, Basic Books, 2013.
11. Ryan, "Intrinsic and Extrinsic Motivations: Classic Definitions and New Directions," see reference 8.
12. Edward L. Deci and Richard Flaste, *Why We Do What We Do: Understanding Self-Motivation*, Penguin, 1996.
13. Matthew D. Lieberman, *Social: Why Our Brains Are Wired to Connect*, Oxford University Press, 2013.
14. David Packard, *The HP Way: How Bill Hewlett and I Built Our Company*, HarperCollins, 1995.
15. W. Edwards Deming, *Out of the Crisis*, MIT Press, 1986.
16. David Scott Yeager and Matthew J. Bundick, "The Role of Purposeful Work Goals in Promoting Meaning in Life and in Schoolwork During Adolescence," *Journal of Adolescent Research*, Vol. 24, No. 4, 2009, pp. 423-452.
17. Pink, *Drive: The Surprising Truth about What Motivates Us*, see reference 9.
18. Angela Duckworth, *Grit: The Power of Passion and Perseverance*, Scribner, 2016.
19. Andrew Ortony, Gerald L. Clore and Allan Collins, *The Cognitive Structure of Emotions*, Cambridge University Press, 1997.
20. Pink, *Drive: The Surprising Truth About What Motivates Us*, see reference 9.
21. Robert Greene, *Mastery*, Penguin Books, 2012.
22. Robert W. White, "Motivation Reconsidered: The Concept of Competence," *Psychological Review*, Vol. 66, No. 5, 1959, pp. 297-333.
23. Deci, *Why We Do What We Do: Understanding Self-Motivation*, see reference 12.
24. Ortony, *The Cognitive Structure of Emotions*, see reference 19.

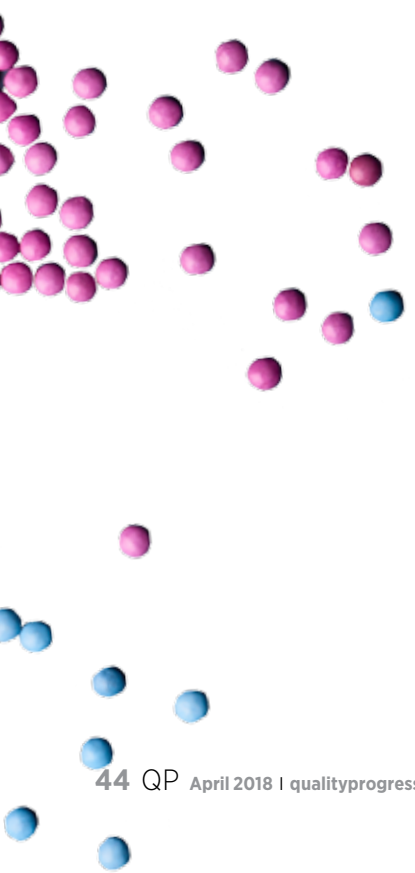
David Kachoui is the director of business development for Natech Plastics Inc. in Ronkonkoma, NY. He holds an MBA from Columbia University in New York City. Kachoui is an ASQ member and a Project Management Institute-certified project management professional.

DEFECT VS. DEFECTIVE

Know the Differences

Understand the type of data you're dealing with before beginning analysis

by Matthew Barsalou



Data are not the same as information. Data alone serve little purpose. To be useful, data must be transformed into information. As long-time QP authors Roger W. Hoerl and Ronald D. Snee once wrote: "We need both theoretical understanding and practical experience to properly translate … data into actionable information."[1]

You can use statistical methods to translate data into actionable information for assessment or decision making. But you must understand your data before performing an analysis. You should know how the data were collected, where they came from and what type of data you're dealing with.

A detailed sampling plan should be created before collecting data. The sampling plan should include where the data will be collected, the measuring device to be used, what type of sampling will be performed and who will perform the sampling. There are times when sampling is not performed because the data are already available. Although this may be quicker than taking a new sample, it entails its own risks. The background of data that has been provided should be known because critical mistakes can be made if the data were collected in a way that differs from what the analyst anticipates.

For example, I once received data to determine baseline performance, and all values were in specification. This seemed odd because I knew the process had a high scrap rate. I inquired, and the production engineer discovered that the operator who was performing the checks did not record any of the parts that were out of specification. This could have led to an incorrect conclusion.

Whether provided or collected per a sampling plan, data should be graphed and visually assessed. Does it look plausible? Snee and Hoerl recommend evaluating:

+ The science, engineering and structure of the process or product from which the data were collected.
+ The data collection process used to obtain and prepare the data for analysis.
+ How the measurements were made.[2]

The terms defect and defective are often used when discussing failure types and failed parts, respectively.

Types of data

Understanding what type of data is available is important for determining which type of statistical tests will be performed. Data can be classified as qualitative or quantitative, as shown in Figure 1.

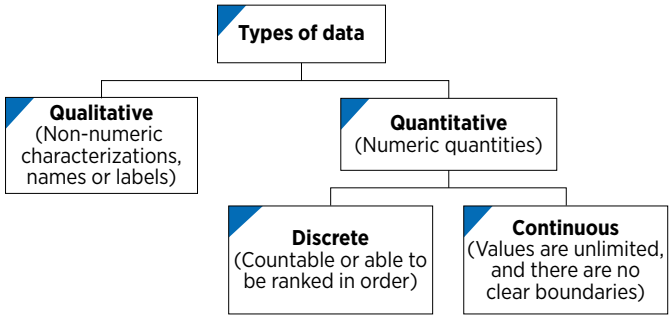
Qualitative data consist of labels or descriptions. Numbers may be used on qualitative data for coding such as "1 = supplier A" and "2 = supplier B," but such numbers should be interpreted as labels—not as any form of measurement. Quantitative data can be either continuous or discrete. Continuous data also are called variable data, and discrete data also are called attribute data.[3] Measurement data are continuous and count data are discrete. An item may consist of all types of data such as product X (qualitative) with one part (discrete) performing best (discrete) and having a diameter of 17.24 mm (continuous).

Continuous data are generally better for a statistical analysis than discrete data because continuous data provide more information than discrete data. You can get more information from knowing that a part was out of specification with a diameter of 12.24 mm than simply knowing you had one out-of-specification part.

But you also should consider what you want to learn from the data. For example, the number of failed parts (discrete data) is more relevant than the actual measurements (continuous data) if you are trying to determine if product A fails more often than product B. On the other hand, knowing the individual dimensions (continuous data) is more important when trying to identify the source of variability.

FIGURE 1

Types of data



Defect and defective

The terms defect and defective are often used when discussing failure types and failed parts, respectively. These two separate terms often cause confusion, so consider an organization producing one meter by one meter sheets of steel.

The part is the defective, and the flaw, blemish and failure is the defect. So, one sheet is a defective sheet of metal. It could have a scratch (one defect) or maybe even two scratches, a dent and a dimension out of specification. In that case, you still have one defective part—and that defective would have four defects.

Cast iron may have porosity or blowholes on a machined surface. In such situations (other than for the analysis), it generally would make more sense to only care about the number of defective parts. If you built cars, you probably would still care about the number of defective vehicles, but the number of defects may be more interesting (one car with a scratched door, missing tire and an oil leak). Here is how ASQ explains defect and defective:

+ **Defect:** A product's or service's nonfulfillment of an intended requirement or reasonable expectation for use, including safety considerations. There are four classes of defects: class 1, very serious, leads directly to severe injury or catastrophic economic loss; class 2, serious, leads directly to significant injury or significant economic loss; class 3, major, is related to major problems with respect to intended normal or reasonably foreseeable use; and class 4, minor, is related to minor problems with respect to intended normal or reasonably foreseeable use. Also see "blemish," "imperfection" and "nonconformity."
+ **Defective:** A defective unit; a unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.[4]

Another long-time QP author, Forrest W. Breyfogle, explains the terms as:

+ **Defect:** A nonconformity or departure of a quality characteristic from its intended level or state.
+ **Defective:** A nonconforming item that contains at least one defect or has a combination of several imperfections causing the unit not to satisfy intended requirements.[5]

Confusing defects and defectives could result in the selection of an inappropriate statistical method. For example, a P chart is used for defective parts and a C chart is used for defects. The easiest way to use the terms would be to always say "defective part" or use the name of the part such as "defective sheet of metal" for defectives, and to think of the defect as being interchangeable with the problem name such as "scratches."

FIGURE 2

Defective pairs with defects

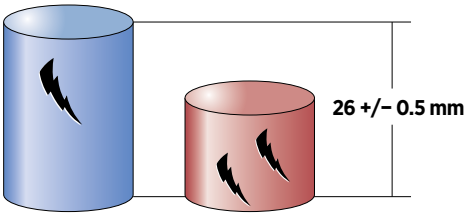


Figure 2 shows two defectives: the blue and red cylinders. Suppose the specification called for the cylinders to have a length of 26 +/- 0.5 mm, and the parts are required to be blemish free. The blue part is defective with one defect: the scratch.

The red part is also defective. However, it has two scratches and a measurement deviation (too short). Therefore, the red part has three defects. In total, the illustration depicts two defectives and four defects.

It is essential to know where your data came from and what type of data you are dealing with when selecting a statistical method to analyze the data with.

Failure to do so could result in taking action based on an incorrect conclusion or applying the wrong statistical method. QP

Matthew Barsalou is a statistical problem resolution Master Black Belt (MBB) at BorgWarner Turbo Systems Engineering GmbH in Kirchheimbolanden, Germany. He has a master's degree in business administration and engineering from Wilhelm Büchner Hochschule in Darmstadt, Germany, and a master's degree in liberal studies from Fort Hays State University in Hays, KS. Barsalou is an ASQ senior member and holds several certifications.

REFERENCES

1. Roger W. Hoerl and Ronald D. Snee, *Statistical Thinking: Improving Business Performance*, second edition, John Wiley and Sons, 2012.
2. Ronald D. Snee and Roger W. Hoerl, "Statistics Roundtable: Inquiry on Pedigree," *Quality Progress,* December 2012, pp. 66-68.
3. Jack B. ReVelle, *Quality Essentials: A Reference Guide from A to Z,* ASQ Quality Press, 2004.
4. ASQ, Quality Glossary, https://asq.org/quality-resources/quality-glossary/d.
5. Forrest W. Breyfogle III, *Implementing Six Sigma: Smarter Solutions Using Statistical Methods,* second edition, John Wiley and Sons, 2003.

Standard Issues

ISO 9004:2018

Sustaining Success

The latest revision to ISO 9004 focuses on organizational success

by Paul Palmes

An international standard's progression from one revision to the next is always a much-discussed topic in the standards community. The latest revision to ISO 9001, for example, continues to dominate conversations because of its new approach and emphasis on context, interested parties and risk-based thinking.

As a close relative, *ISO 9004—Managing for the sustained success of an organization—a quality management approach* always had been of interest because it followed ISO 9001 through its revisions, offering additional insights to promote excellence beyond compliance. ISO 9004 and ISO 9001 were a consistent pair—ISO 9004 provided clause-by-clause guidance to ISO 9001's compliance requirements.

ISO 9004:2018, however, has taken a major step in defining itself as a standalone document that is related to—but separate from—ISO 9001:2015. It's all about business, with a primary focus on organizations' sustained success.

Recognizing the potential impact of the 2018 revision, Alka Jarvis (past chair of the U.S. Technical Advisory Group to International Organization for Standardization (ISO) Technical Committee 176) and I combined our resources and experience to further expand on ISO 9004's contributions to quality management's body of knowledge in the book *Business Sustainability: Going Beyond ISO 9004:2018*.[1]

New emphasis

A first look at ISO 9004:2018's *Clause 4—Quality of an organization and sustained success* indicates the document's new emphasis on organizational success. It states:

"The 'quality of an organization' is the degree to which the inherent characteristics of the organization fulfill the needs and expectations of its customers and other interested parties, in order to achieve sustained success."[2]

The focal point is no longer generic quality and improvement but the overall success of an organization. The note that follows this statement further clarifies the standard's business-centric approach and provides a foundation for the rest of the standard:

"NOTE 1: The term 'quality of an organization' is from the definition of 'quality' given in ISO 9000, 3.6.2 ('the degree to which a set of inherent characteristics of an object fulfills requirements'), and from the definition of 'requirement' given in ISO 9000, 3.6.4, ('needs or expectations that are stated, generally implied or obligatory'). It is also distinct from the purpose of ISO 9001, which focuses on the quality of products and services in order to give confidence in the ability of an organization to provide conforming products and services and to enhance its customers' satisfaction."[3]

The standard goes on to say, "To achieve sustained success the organization should go beyond the quality of its products and services and focus on anticipating and meeting the needs and expectations of its interested parties and not just those of its customers alone, with the intent of enhancing their satisfaction and overall experience."[4]

In our book, Jarvis and I expanded on these concepts:

"Retention of buying customers and a strong competitive position creates a solid financial position; a noticeably strong financial performance is foundational to sustainable success. The most visible sign of sustainability is market growth. Whether this growth can be sustained for a longer period depends on how poised your organization is to identify and embrace new strategies and recognize where new challenges will be. Sustained success requires leaders of organizations to look for new opportunities to innovate, grow, and retain market share."[5]

Subsequent clauses continue this directed approach by providing examples that go beyond traditional quality guidance. The net effect is a highly impactful document that offers answers to questions about how an organization can prosper.

For organizations still grappling with context, for example, ISO 9004:2018 combines the interactions of interested parties and internal and external forces in an expanded list of market and operational possibilities that many organizations will find helpful. This guidance is relevant, business-centric and insightful, as is the entire standard.

It is the standard's expanded attention to practical and business-minded content that provides an opportunity to dig deep into its leadership and policy clauses:

"While policies are important, personal policies of the organization's leadership are extremely so. The progression from entrepreneurship to bureaucracy can be slowed significantly through demonstrated policy-based behaviors that true leaders exhibit throughout the day … Leaders use, practice and embrace policy to everyone's advantage; the organization is understandable and its practices consistent through just watching and listening to its leaders. Rather than emphasizing reliance on requiring an employee to remember organization policies, leaders know that employees learn most directly through observation of how they interact with all employees."[6]

Meaningful guidance

Although the ISO 9004:2018 writing committee didn't have the luxury of writing complete narratives, it still lived up to its mandate. Businesses of all shapes and sizes—especially those that are ISO 9001:2015 compliant—now have access to meaningful guidance to improve their standing in the marketplace and, as the title suggests, achieve sustained success.

The words "sustained success" were chosen carefully and may be confusing to some people because ISO and quality management system-related standards consistently promote improvement in their titles. ISO 9004:2018 broke with that tradition to convey the message that no matter what an organization attempts, it must first adopt sustainability as a bedrock principle.

The guidance provided in ISO 9004:2018 was predicated on presenting a complete description of the factors that should be effectively managed by good stewards of their organizations. Its approach to improvement is from a consistent perspective of sustainability that serves everyone in the quality and business communities with its approach and guidance. QP

REFERENCES

1. Paul Palmes and Alka Jarvis, *Business Sustainability: Going Beyond ISO 9004:2018*, ASQ Quality Press, 2018.
2. International Organization for Standardization (ISO), *ISO 9004:2018—Managing for the sustained success of an organization—a quality management approach*.
3. Ibid.
4. Ibid.
5. Palmes, *Business Sustainability: Going Beyond ISO 9004:2018*, see reference 1.
6. Ibid.

Paul Palmes is principal consultant with Business Systems Architects Inc. in Fargo, ND, and Prescott, WI. He is chair of the U.S. Technical Advisory Group to the International Organization for Standardization, Technical Committee 176 (ISO/TC 176), and chair of ISO/TC 176, subcommittee 1, responsible for ISO 9000:2015. He is the coauthor of *Business Sustainability: Going Beyond ISO 9004* (ASQ Quality Press, 2018) and *ISO 9001:2015: Understand, Implement, Succeed!* (Prentice Hall, 2015), and author of *Process Driven Comprehensive Auditing*, second edition (ASQ Quality Press, 2009) and *The Magic of Self-Directed Work Teams* (ASQ Quality Press, 2006).

SIGMAXL V8

MULTIPLE COMPARISONS MADE EASY!

SigmaXL Inc. is a leading provider of user friendly Excel Add-ins for Lean Six Sigma graphical and statistical tools and Monte Carlo simulation.

INCLUDES

ANALYSIS OF MEANS (ANOM) CHARTS, MULTIPLE COMPARISONS (POST-HOC), CHI-SQUARE TESTS & TABLE ASSOCIATIONS AND MORE!

Visit us at booth 601 at the ASQ World Conference on Quality and Improvement.

SigmaXL
Simply Smart Software

1-888-SigmaXL (1-888-744-6295)

Sales@SigmaXL.com

Quantity and trainer discounts available.

DiscoverSim™
Discovery through Simulation

SPONSOR AND EXHIBITOR GUIDE

2018 WORLD CONFERENCE ON QUALITY AND IMPROVEMENT
April 30 – May 2, 2018 | Washington State Convention Center | Seattle, WA

Thousands will flock to ASQ's World Conference on Quality and Improvement this year to attend more than 100 sessions focused on this year's theme—The Innovation of You—and to meet and learn from the dozens of exhibitors and sponsors that will crowd the exhibit floor. Even if you can't attend, this guide provides the information you need to choose the tools and products to meet your goals. If you are in Seattle, be sure to visit the company booths listed within.

An interactive floor plan can be found at http://s23.a2zinc.net/clients/ASQ/WCQI2018/Public/Enter.aspx. The conference this year takes place at the Washington State Convention Center in Seattle.

A special thank you to all of our exhibitors and sponsors!

SPONSOR AND EXHIBITOR GUIDE

SPONSORS	Booth
ASQ Aviation, Space, and Defense Division – International Team Excellence Award Supporter	834
The Boeing Company – Networking Event Transportation Sponsor	605
BSI – Lanyard Sponsor	418
EtQ, LLC – Gold Sponsor	219
Minitab Inc. – Registration Area Sponsor	213
Northrop Grumman – Mobile App Sponsor Non-exhibiting	
Veeva Systems Inc. – Premium Sponsor	220

RECRUITING EXHIBITORS

Alcon Laboratories	225
BSI	418
Kaeppel Consulting	114
Raytheon Missile Systems	600

EXHIBITORS	Booth
A2LA – American Association for Laboratory Accreditation	327
AIAG – Automotive Industry Action Group	322
Alcon Laboratories	225
AQS Solutions	509
ARMATURE Corporation	719
AssurX Inc.	332
CABEM Technologies	602
Bisk	115
BPA Solutions USA LLC	318
California State University, Dominguez Hills	101
CANEA ONE	315
Creato Performance Solutions	109
DEKRA Certification Inc.	507
DevonWay	504
DNV GL	324
Dozuki	303
DQS Inc.	203
EMNS Inc. – Global Supplier Quality Assurance (GSQA)	100

EXHIBITORS	Booth
FDA Quality and Regulatory Consultants LLC	127
Gemba Academy	305
GOAL/QPC	608
Ideagen Gael Ltd.	227
Intelex Technologies Inc.	212
International Accreditation Service (IAS)	102
Intertek	404
IQS Inc.	709
Isolocity	209
Kaeppel Consulting LLC	114
LRQA	508
MasterControl Inc.	607
MDL Business Consulting	300
MoreSteam.com	412
MWA Consulting Inc.	606
National Association for Healthcare Quality	113
The National Graduate School of Quality Management at NECB	201
North Carolina State University – Lean Six Sigma Programs	400

SPONSOR AND EXHIBITOR GUIDE

EXHIBITORS	Booth
NQA	407
NSF–ISR	300
The Ohio State University	
Fisher College of Business	
Master of Business	
Operational Excellence	302
OpusWorks by The Quality Group	319
Park Avenue Solutions	204
Peoplelink Group	713
Pilgrim Quality Solutions	406
PLATO North America Inc.	119
Predisys Inc.	306
Pro QC International	331
Pyzdek Institute LLC	405
QI Macros for Excel	200
QiSOFT	424
QT9 Software	401
QualiWare Inc.	309
Qualtrax Inc.	108
Raytheon Missile Systems	600
Rx–360 Consortium	402
SAS Institute Inc., JMP Division	500

EXHIBITORS	Booth
SGS North America Inc.	717
Siemens PLM Software	208
SigmaXL	601
Sparta Systems Inc.	330
SQA Services Inc.	226
Statpoint Technologies Inc.	408
System Improvements/TapRooT®	301
Taylor & Francis Group	604
TRACtion Services LLC	409
Tulip Interface	118
uniPoint Software Inc.	218
Verify Inc.	304
VKS	323
Washington State University	
Engineering and	
Technology Management	126
X–Stream Leadership Group LLC	202
Zeiss Industrial Metrology	205

ASQ FAMILY OF COMPANIES	Booth
ANAB/ANSI-ASQ National Accreditation Board	715
ASQ Media Sales/Naylor	818
Exemplar Global	708

SPONSOR AND EXHIBITOR GUIDE

A SPECIAL THANK YOU TO THESE FEATURED SPONSORS

ASQ Aviation, Space, and Defense Division – International Team Excellence Award Supporter

Booth 834

The Boeing Company – Networking Event Transportation Sponsor

3003 West Casino Road
Everette, WA 98024
Phone: 312-544-2000
www.boeing.com
Booth 605

Boeing is the world's largest aerospace company and leading manufacturer of commercial jetliners and defense, space and security systems. A top U.S. exporter, the company supports airlines and U.S. and allied government customers in 150 countries.

BSI – Lanyard Sponsor

12950 Worldgate Drive, Suite 800
Herndon, VA 20170
Phone: 703-674-1805
www.bsigroup.com
Booth 418

BSI is your business improvement solutions partner. With an integrated approach that includes training, assessment and compliance tools, BSI can help you drive continual improvement across your organization.

EtQ LLC – Gold Sponsor

399 Conklin St., Suite 208
Farmingdale, NY 11735
Phone: 516-293-0949
www.etq.com
Booth 219

EtQ is the leading quality, EHS and compliance management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration.

Minitab – Registration Area Sponsor

1829 Pine Hall Road
State College, PA 16801
Phone: 800-448-3555
www.minitab.com
Booth 213

Minitab® is a world-class leader in easy-to-use statistical software for quality improvement. The suite includes Companion a complete process improvement toolkit and SPM® a highly accurate platform for data mining and predictive analytics.

Northrop Grumman – Mobile App Sponsor

2980 Fairview Park Drive
Falls Church, VA 22402
Phone: 408-203-9604
www.northropgrumman.com
Non-exhibitor

Northrop Grumman is a leading global security company providing innovative systems, products and solutions in unmanned systems, cyber, C4ISR and logistics and modernization to government and commercial customers worldwide.

Veeva Systems Inc. – Platinum Sponsor

4280 Hacienda Drive
Pleasanton, CA 94588
Phone: 925-452-6500
www.veeva.com
Booth 220

Veeva helps companies improve efficiency, visibility and control in quality management with a secure cloud solution that unifies processes, documents and data.

Attending the 2018 ASQ World Conference?

Let us show you a modern, secure solution for managing Manufacturing Quality

Visit Veeva at Booth #220

Join us for "The Future Arrived Yesterday – Quality's Role in Digital Transformation" from 3-4 pm on Monday, April 30

Veeva Vault QualityOne

Veeva is a leader in cloud-based software. Committed to innovation, product excellence, and customer success, Veeva has more than 600 customers, ranging from the world's largest companies to emerging small businesses. Learn more at qualityone.veeva.com

SPONSOR AND EXHIBITOR GUIDE

A SPECIAL THANK YOU TO THESE FEATURED EXHIBITORS

CANEA ONE

1765 Greensboro Station Place, Suite 900
Tysons Corner, VA 22102
Phone: 844-872-2632
www.canea.com
Booth 315

The CANEA ONE solutions platform is a truly integrated quality management system that links corporate strategy to business processes, change initiatives and internal document control.

EMNS Inc./GSQA Global Supplier Quality Assurance

2815 Centre Circle Drive
Downers Grove, IL 60515
Phone: 866-438-4772
www.emns.com
Booth 100

International Accreditation Service (IAS)

3060 Saturn St., Suite 100
Brea, CA 92821
Phone: 562-364-8201
www.iasonline.org
Booth 102

Established in 1975, IAS provides accreditation for companies in multiple industries to standards and regulations, including ISO standards 17021, 17020, 17065, 17024, 17025, 15189, EPA, FDA, etc.

IQS Inc.

24950 Country Club Blvd., Suite 120
North Olmsted, OH 44070
Phone: 800-635-5901
www.iqs.com
Booth 709

Engineered to elevate your QMS into a strategic business tool, IQS helps manage compliance and control the cost of quality, reduce risk and improve visibility.

SigmaXL

305 King St. West, Suite 503
Kitchener, ON N2G 1B9
Canada
Phone: 416-236-5877
www.sigmaxl.com
Booth 601

Bringing you lean Six Sigma statistical tools, templates and Monte Carlo simulation in the already familiar Excel. Start your free 30-day trial of SigmaXL or DiscoverSim today!

SPONSOR AND EXHIBITOR GUIDE

ASQ DIVISIONS, SECTIONS AND FORUMS

	Booth
Audit Division	433
Automotive Division	339
Aviation, Space & Defense Division	834
Biomedical Division	539
Chemical and Process Industries Division	838
Customer-Supplier Division	531
Design and Construction Division	630
Education Division	435
Electronics and Communications Division	534
Energy and Environmental Division	333
Fellows Technical Group	735
Food, Drug, and Cosmetic Division	538
Government Division	434
Healthcare Division	632
Human Development and Leadership Division	830
Innovation Division	731
Inspection Division	738
Lean Enterprise Division	430
Measurement Quality Division	739
Quality Management Division	730
Reliability and Risk Division	535
Section Affairs Council (SAC)	335
Service Quality Division	740
Six Sigma Forum	631
Social Responsibility Technical Community	439
Software Division	832
Statistics Division	639
Team and Workplace Excellence Forum	635

Marketplace

NOISE SUPPRESSOR RESISTORS

Able to withstand high-voltage pulses and frequencies

Vishay's series of wire-wound noise suppressor resistors offers improved voltage performance and reliability for automotive ignition systems in reciprocating engines. The Vishay Dale NSR-HP series devices feature a coating that increases reliability by protecting the resistive element against moisture and mechanical shock, while enabling high-voltage performance to 45 kV and high operating temperatures to +200°C. The resistors can withstand high-voltage pulses at high frequencies and feature a dielectric withstand voltage of 1,000 VAC.

Ideal for reducing radio frequency interference during electrical discharges in gasoline engines, the NSR-HP series can be used in spark plug leads and in spark plug caps. The resistors are RoHS-compliant, halogen-free and Vishay green.

www.vishay.com | 02-563-6866

SOFTWARE

Simplifies reporting of weather data

Onset's HOBOlink is a web-enabled software platform designed for HOBO RX3000 remote monitoring systems and features integration with Google Maps and Weather Underground (WU). HOBOlink can simplify the monitoring, management and reporting of weather data.

HOBOlink works with Onset's research-grade HOBO RX3000 weather stations to provide research scientists, meteorologists and others with instant access to site-specific environmental data. Delivered as a cloud service, it allows users to access current and historical data via their web browsers or mobile devices, set alarm notifications and relay activations, and control HOBO RX3000 web-based data logging systems.

The integration with WU means HOBOlink users can push weather data to WU through an interface. The Google Maps integration allows users to see all of their geographically distributed HOBO devices and drill down on the details. A responsive design adjusts the view of HOBOlink on the screen so users can take advantage of all the features from their mobile phones and tablets.

www.onsetcomp.com | 800-564-4377

STRAIN GAGE

Products available with safety certifications

BLH Nobel has announced that four of its strain gage load cell product families are available with EN ISO 13849 and IEC 61508 functional safety certifications.

The EN ISO 13849 functional safety standard incorporates statistical analysis to help better predict component, device and circuitry reliability in the safety-related parts of industrial machinery control systems. This determination represents the probability of failure to danger over time expressed as a performance level. The IEC 61508 standard for electrical/electronic/programmable electronic safety-related systems further defines methods to achieve product functional safety.

These certifications allow the BLH Nobel load cells to be specified in a wider range of critical applications, including crane weighing and overload monitoring; process industry weighing and monitoring; offshore tank weighing; machinery monitoring; and safety-critical weighing and force measurements.

www.blhnobel.com | 781-298-2200

CAMERA

High dynamic range offers significant detail

Vision Research has introduced the Phantom v2640, a 4-Megapixel camera. It features a proprietary 4-Megapixel CMOS image sensor that delivers image quality at up to 26 Gpx/sec, while reaching 6,600 frames per second at full 2,048 x 1,952 resolution, and 11,750 fps at 1,920 x 1,080.

The v2640 features high dynamic range and the lowest noise floor of any Phantom camera—making it an ideal tool for researchers, scientists and engineers who need to capture clean, high-resolution images at ultra-high speeds. The high dynamic range shows significant detail, especially in high-contrast environments, while the low noise is particularly beneficial when analyzing the dark regions of an image. It also has exceptional light sensitivity, with an ISO measurement of 16,000D for monochrome cameras and 3,200D for color cameras.

www.phantomhighspeed.com | 248-481-6638

LINE LASERS

Technology for levelling and alignment

Leica Geosystems' Lino series of cross and point line lasers are specially designed to ensure laser visibility. The Li-ion rechargeable batteries enable users to work without interruptions. The smart laser technology offers complete levelling and alignment.

Vertical and horizontal alignment of the lines and points is easy with the self-levelling lasers. Leica Lino point and cross-line lasers can be operated with Li-ion rechargeable or alkaline batteries, or they can be connected directly to the power supply. The triple power concept ensures uninterrupted use.

The lasers are manufactured out of high-grade strong materials and are, therefore, suitable for use on construction sites. The optics are protected by a high-grade aluminum frame and impact-absorbing rubber components.

www.leica-geosystems.com | 41-71-727-3131

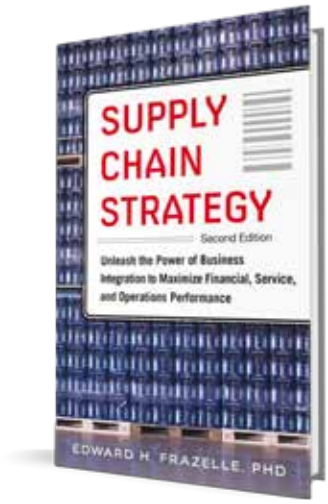
MONITOR

Condition monitor for non-hazardous areas

Turck has announced the IM12-CCM (cabinet condition monitor) cabinet guard, a device capable of monitoring moisture and temperature limits while also detecting incorrectly closed doors. The device is intended for use in hazardous areas. The device monitors unauthorized access to switch cabinets, providing protection against manipulation in compliance with IT security regulations.

The IM12-CCM features an internal data logger with time stamp and stores data for up to two years, allowing users to detect creeping changes over long periods of time. An interface enables two cabinet guards to be operated in master-slave mode simultaneously, monitoring correct door closing and other limit values at two points in the control cabinet. The master processes the data of the slave and sends a signal to the controller.

turckusa@turck.com | www. turck-USA.com



Supply Chain Strategy: Unleash the Power of Business Integration to Maximize Financial, Service, and Operations Performance

EDWARD H. FRAZELLE ▮ MCGRAW-HILL ▮ 2017 ▮ 384 PP. ▮ $65 (SECOND EDITION, BOOK).

Unleashing the power of business integration to maximize financial, service and operation performance is critical for a business to sustain competitive advantages. Frazelle provides cases that validate his RightChain methods. The book can be used by executives as a resource for developing their own supply chain strategy. Frazelle provides evidence that sustainable competitive advantage is not about lowest price, but cooperation throughout the supply chain.

Businesses must be faster to market and flexible to service their customers. Hence, the better business approach requires investment in a supply chain strategy for supply chain cooperation. Partners in the supply chain share information, material status, production capacity effectiveness and on-time delivery performance. All supply chain partners must benefit from being in the supply chain.

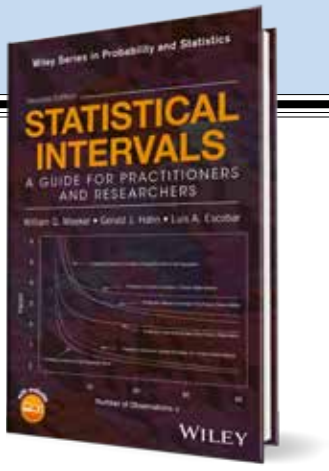
Frazelle's book is timely because there are urgent business issues caused by continued price pressure and high-quality products and services with shorter delivery lead times. The case studies show how organizations can meet supply chain goals with the latest supply chain innovations. The logic and tools provided will help businesses prioritize the financial and operational impact of risk. Understanding supply chain issues will enable businesses to form mitigation efforts on their most impacted processes and suppliers.

This book is recommended for senior management because supply chains be agile, sustainable and cost-efficient as they meet customer demands. Getting the CEO's support will be the supply chain director's most important task.

John J. Lanczycki Jr., West Springfield, MA

Additions to your quality library

Footnotes



Statistical Intervals: A Guide for Practitioners and Researchers

WILLIAM Q. MEEKER, GERALD J. HAHN AND LUIS A. ESCOBAR ▮ JOHN WILEY & SONS ▮ 2017 ▮ 648 PP. ▮ $110 (BOOK).

This book is a comprehensive overview of interval estimation that serves as an excellent reference for individuals engaged in statistical research. The topics added to the second edition are timely, including three new chapters on Bayesian analysis and two chapters examining bootstrapping for nonparametric and parametric statistics. There is a companion website that includes additional figures and data sets, and new information related to interval estimation. Information about the StatInt R package also is provided on the website and this is an important adjunct to the book.

The first four chapters of the book are a review of sampling, different types of intervals and constructing intervals using the normal distribution. Most of this is a review for statisticians, but it does include information on tolerance intervals and, particularly timely, using confidence intervals instead of p-values for analyses.

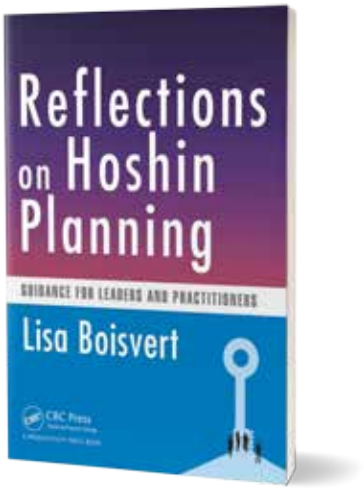
Each chapter that follows describes intervals using different probability distributions or distribution-free intervals and the implications for sample size calculations. This is followed by a set of basic case studies. Advanced case studies follow the next group of chapters on likelihood, bootstrap and Bayesian interval estimates. There is a short epilogue describing the creation of the book, followed by 10 appendixes covering notation, definitions, distributions, likelihoods, prior distributions and tables.

Overall, this text covers classic and basic statistical intervals as well as simulation and bootstrap techniques for intervals, resulting in a complete reference for researchers. For future editions, the authors might think about moving the tables to the website. Truly an amazing compendium on an area of increasing importance in research as data sets increase in size and our use of p-values becomes less meaningful.

I. Elaine Allen, San Francisco

Reflections on Hoshin *Planning: Guidance for Leaders and Practitioners*

LISA BOISVERT ▮ CRC PRESS ▮ 2016 ▮ 224 PP. ▮ $35.94 (BOOK).



This book is the author's unique approach to *hoshin* planning based on several topics and environments she has personally witnessed. While the approach is unique, the book follows a logical framework. Chapters one thru four address the structure for *hoshin* planning. Chapters five thru six address the softer issues of leadership and business disruption. The final chapters are focused on how *hoshin* is treated in fluid environments—mergers and acquisitions in startup organizations.

The book begins with three damaging practices for organizations when installing a *hoshin*. This is defined as a breakthrough strategy. They are: too many priorities, insufficient detail to execute, and lack of active review and follow-up. Included is a discussion of catchball—an element of gaining commitment down through levels of management to provide needed resources to meet the *hoshin* goals.

Chapter four discusses performance measurement. Table 4.5 is particularly insightful in which nine good practices are listed and explained for effective measurement.

Chapter five covers the four star qualities of *hoshin* leaders: inclusion, self-knowledge and maturity, realistic sense of employees' moods, and the confidence to share leadership in a hopeful, positive attitude.

The end of the book notes that *hoshin* planning is a powerful tool that can be used to bring the parties and individuals together toward a common goal. But it's also fragile and can be overlooked with all the smaller scale work going on to integrate the organizations and develop standard work. Even though startups may think entrepreneurially, they can benefit by leveraging suppliers' and stakeholders' knowledge in the planning.

The book concludes with nine appendixes that explain the *hoshin* tools. This book is good for anyone involved in strategy and implementing major change in an organization—including C-suite leaders.

Bill Baker, Santa Fe, NM

It's About Patient Care: Transforming Health Information Technology the Cleveland Clinic Way

C. MARTIN HARRIS M.D., AND GENE LAZUTA ▮ MCGRAW-HILL EDUCATION ▮ 2016 ▮ 240 PP. ▮ $32 (BOOK).

This book is about lessons learned at the Cleveland Clinic covering past decades while bringing about a change in IT employed at the clinic. The book is organized into five chapters.

The first chapter addresses how the internet is a valuable tool for complex technology-based solutions. The authors argue that health IT systems will experience a significant increase in use only when they are able to connect all clinical care providers, administrative users and patients to all the information services they need.

The second chapter asserts that technology-driven transformation of any healthcare organization must be based on a comprehensive consensus position that includes the representative voices of every part of the organization's critical resource, namely its people. The authors state that the underlying relationship structure of the internet mirrors the way society is organized. Hence, the internet could be used to establish and cultivate relationships with patients and their families.

The essence of chapter three is that online use is catching on rapidly, leading to the public purchasing and using a wide range of digital medical devices and services. In this context, bringing the right patient and clinician together through a technology-supported service is an increasingly important competency.

The fourth chapter is about electronic health record (EHR) adoption and use. The authors contend that the EHR is an important tool that links clinicians to other clinicians, to their patients, and to the vast amount of patient and practice-related data.

The last chapter emphasizes an overall focus on trust, access and value. Should this happen, the architecture, capabilities and utility of a secure virtual practice space will become easier to understand, build and articulate.

The book is replete with real-world experiences and is presented in a story-book style, which makes it easy to understand. There are many references to quality and continuous improvement. Because the book presents actual events that happened in a world-class organization such as the Cleveland Clinic, it is a valuable addition to the library of anyone involved in healthcare, especially quality and improvement in healthcare.

Anuradha Rangarajan, Harvard, IL

Make the Write Decision

An average adult makes about 35,000 decisions each day, according to various internet sources. Now that *QP*'s 2018 editorial calendar has been released, there's one more to make:

Do you want to write for *Quality Progress*?

If your answer is yes, take a look at the specific topics we're planning to cover:

June **Generations in the Workforce**	October **Quality 4.0**
July **Continuing Education and Your Career**	November **Project Management**
August **Basic Tools and Terminology**	December **Salary Survey**
September **Operational Excellence**	

Visit **www.qualityprogress.com** and click on "Author Guidelines" at the bottom of the page for more details. QP

Advertisers Index

ADVERTISER	PAGE	PHONE	WEB
The Boeing Company	57	312-544-2000	www.boeing.com
BSI Group America Inc.	51	703-674-1805	www.bsigroup.com
Canea One	52	844-872-2632	www.canea.com
CyberMetrics Corp.	OBC	800-777-7020	www.cybermetrics.com
EtQ Inc.	IFC, 53, IBC	516-293-0949	www.etq.com
Exemplar Global Inc.	15	800-549-2440	www.exemplarglobal.org
IQS	56	800-635-5901	www.iqs.com
PQ Systems	47	800-777-3020	www.pqsystems.com
SigmaXL	50	416-236-5877	www.sigmaxl.com
Veeva Systems Inc.	55	925-452-6500	www.veeva.com

NEW MEMBER BENEFIT
ONLINE JOURNAL ACCESS!

ASQ now offers free digital subscriptions to two of our premier academic journals, the *Journal of Quality Technology* and *Quality Management Journal*. Previously offered as paid subscriptions, online access is available to Full members and above with their membership.

The new and improved online versions of the journals feature continuous publication—articles posted as soon as they are complete—and other modernized features including improved search and citations. To access the journals, log in at **asq.org/pub/qmj/** and **asq.org/pub/jqt/**.

For those who still prefer print journals, an annual print volume of both journals will be available for purchase through the ASQ website.

ASQ
The Global Voice of Quality®

TRY this TODAY

A new twist on an established quality concept

A Roll of the Dice

The key to operational excellence is process documentation **by William A. Levinson**

When it comes to documentation requirements, ISO 9001:2015 is much less prescriptive than ISO 9001:2008. According to clause 7.5.1 of the revision, an organization must maintain documented information required by the standard, and any additional documentation the organization deems necessary for the effectiveness of its quality management system (QMS).

What an organization considers necessary is key—under-documentation of key processes can put the organization's quality and efficiency at risk.[1] The organization must ask itself whether its goal is simply to become ISO 9001 certified, or whether it is to use the standard to achieve and maintain operational excellence.

How, for example, do you audit a process for which there is no documented procedure? One approach is to ask the process owner, "What is your process?" But a scene from the Broadway musical "Guys and Dolls" illustrates the possible drawbacks of this approach.

Big Jule, a gangster from Chicago, points a gun at the protagonist, Nathan Detroit, and demands a chance to win back the money he lost to Detroit playing craps. Big Jule insists on using his lucky dice, which are blank. He removed the spots for luck but assures Detroit that he remembers which sides of the dice are which. Needless to say, Big Jule soon wins back his money—and more.

Now suppose Detroit is a quality auditor and Big Jule is the process owner. The same interaction would look something like this:

Detroit: "But there isn't a documented procedure for that process."

Big Jule: "I had the documented procedure removed for luck, but I remember what it is. Do you doubt my memory?"

Even if the process owner recalls the process to the best of his or her knowledge, not having a written procedure makes it much harder to understand or pre-audit the process for inputs, outputs and handoffs to other processes. If multiple shifts or job sites necessitate multiple process owners, each process owner may have a different—albeit legitimate—perception of the process.

Any process that influences the effectiveness of the QMS or affects the quality of the organization's output should be documented—regardless of whether it's explicitly required by ISO 9001:2015—because:

1. Documents specify the best-known way to perform a job and prevent reverting to substandard methods.
2. Documents support ISO 9001:2015's process approach, including handoffs and interactions between processes.
3. Documents are a form of organizational knowledge (clause 7.1.6) that, per Joseph M. Juran, hold the gains and prevent backsliding to inferior methods. This explicit concept predates the standard by roughly 90 years. Henry Ford wrote, "An operation in our plant at Barcelona has to be carried through exactly as in Detroit—the benefit of our experience cannot be thrown away."[2]

The first part of Ford's quote makes it clear that the process definition cannot be left to the memories of individual process owners. The second part reminds us that the invention of writing is, regardless of the requirements of ISO 9001:2015, the foundation of all progress.

Don't gamble with your process. If it has inputs from or outputs to other processes, or if it creates quality records, it almost certainly should be documented. QP

NOTE AND REFERENCE

1. For more information about documented information, read "Guidance on the Requirements for Documented Information of ISO 9001:2015," International Organization for Standardization, https://tinyurl.com/y74dew3e.
2. Henry Ford and Samuel Crowther, *Today and Tomorrow*, Doubleday, Page & Co., 1926.

William A. Levinson is the president of Levinson Productivity Systems P.C. in Wilkes-Barre, PA. He has a master's degree in applied statistics and an MBA from Union College in Schenectady, NY, and holds ASQ certifications in quality auditing, engineering and reliability. Levinson is the author of *The Annotated and Expanded My Life and Work: Henry Ford's Universal Code for World-Class Success* (Productivity Press, 2013).

Gain Visibility & Control Over Your Compliance Processes

EtQ's Quality and EHS Solutions give you control over your processes, while providing you with the visibility into the data to make better decisions, foster continual improvement and create a culture of operational excellence.

www.etq.com • info@etq.com • 800.354.4476

EtQ

Visit us at booth 219 at the ASQ World Conference on Quality and Improvement.

The quality of your product depends on the quality of your software.

With a solid 30-year track record and countless auditor recommendations, GAGEtrak calibration management software has improved quality at over 12,000 facilities worldwide, assuring unwavering accuracy, reliability and standards compliance. And now, with the addition of GAGEtrak Lite to our product line, we have a software solution to meet every need and budget. Contact us now to discuss which one is right for your company or download both and see for yourself.

GAGEtrak and GAGEtrak Lite

Two levels of calibration management. One auditor-recommended name.

Download for free at: GAGEtrak.com/downloads 1-800-777-7020 +1 (480) 922-7300

CyberMetrics®