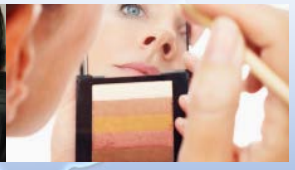
ASQ Food, Drug, & Cosmetic Division
The Global Voice of Quality™





GLOBAL VIEW

August 2015 No. 175

CHAIR'S MESSAGE

by Cathelene Compton

I bring this message to you with feelings of confidence and optimism. The journey of becoming this year's chair for the Food, Drug, and Cosmetic Division has been no easy feat.

The organization faced many changes over the years—loss of division officers, fiscal year changes, and changes in ASQ headquarter goals. What started as a five-year mission turned into six years, and subsequently into a seven-year investment. I started as the Internet liaison and then became secretary, treasurer, vice chair, chair-elect, and now chair.

As I progressed through the succession plan, changes such as the division's fiscal year changing obligated me to remain as the treasurer for an additional six months. The vice chair resigned, which extended my role as treasurer an additional year. I then became vice chair after serving a lengthy term as treasurer. Vice chair was rewarding, inspiring, and fun. I worked diligently with the team to plan notable events for the 2013 World Conference on Quality and Improvement in Indianapolis, IN, and a productive business planning meeting later that year.

As chair-elect, I wanted to revive the Southeast Conference; however, to my disappointment, I was unable to achieve this goal. On a positive note, as a division we continued to work toward member value.

As chair, 2015 has been a rocky road with significant hurdles to overcome. Our vice chair resigned before the World Conference. Our deepest sympathies and prayers were extended to our chair-elect, who suffered a significant loss in her family. While this has been a tough year, as an FDC officer I am confident that the division will survive and overcome these difficulties. Please join me in welcoming Elena Mack, who has returned to fill the vacancy of vice chair. We are so glad to have her back!

So as this year progresses, there are agenda items and goals that are important to me, as chair, and to the success of the division. The FD&C conferences are important to the division. FD&C conferences were designed to be joint conferences with the FDA; thus, allowing members to have access to the FDA with open discussion panels and intimate lunches. My expectation is for the joint FDA/FD&C conferences to remain in place and function as they were intended. I believe these events yield the most member value. Quality professionals are always anxious to ask their questions of "industry best practice" to the FDA; thus, these conferences are a prime opportunity for members.

As chair, this year's goals include revival of these conferences to what they once were. The organization plans to participate in this year's second annual Joint Technical Communities Conference (JTCC) in Orlando, FL, this October. With this participation it will be difficult to host the Southeast Conference this year; however, the Southeast Conference is on the agenda to be revived by 2016. The plan is to move this conference to Atlanta, GA, even though it has been traditionally held in Raleigh, NC. With FDA's budget restrictions for travel, and to ensure FDA participation, the conference must move to the location closest to the district office—Atlanta. Our hope is that our long-time participants for the Raleigh location will be able to follow the conference to Atlanta.

We had a successful Northeast Conference in April in New Jersey. CHA and CPGP refresher courses and related exams were offered. As part of the division's goals "to bring back what once was," I have asked our new vice chair to assist with next year's Northeast Conference to bring back the joint FDA/FD&C conference while integrating the new objective of CHA and CPGP refresher courses as a bonus feature of the conference.

There will be no West Coast Conference this year. Last year the conference evolved from a one-day nutraceutical conference to multi-day full-blown food conference held at Disney. The conference was a huge success, with thanks to Rosemarie Christopher. This event was the start of our refresher courses and learning center modules for CHA and CPGP. The same team will host other events this year including participation in International Food Technologies Conference that was held in July in Chicago, IL. The team had great success in selling our CHA books and promoting the CHA certification. The team will also participate in hosting a CHA refresher course in concert with the National Oceanic and Atmospheric Administration (NOAA).

The Midwestern Conference is scheduled for October, and we expect the conference to be as successful as it has always been. Thank you to June Morita, long-time

Inside This Issue

Our Vision

To be recognized as the resource of choice for quality systems and leadership development in food, drug, and cosmetic regulated industries.

Our Mission

To increase member value by conducting activities and involving members to fulfill the division's vision.

Editor: Arvind Badkas

CHAIR'S MESSAGE cont.

program chair and our thorough, tough audit chair, for championing that conference.

I will keep members posted on the Southeast Conference, as a miracle might happen this year; otherwise, please join us at the JTCC in Orlando.

As a division we have set in motion some very specific goals, including to promote our two certifications: CHA and CPGP. With new food regulations commencing, CHA is very important to the division and our members alike.

We are excited to be rolling out new refresher courses through the ASQ Learning Center. These refresher courses will also be offered at the JTCC prior to the exams. As always, the division is focused on giving back value to its members.

When I started in the division as an Internet liaison, I listened to all the great success about discussion groups and networking with professionals. This inspired my vision of starting discussion groups in all areas of the country. Through the wisdom and time in the division, I have realized that this can only happen with lots and lots of volunteers. I do think we have fallen short as a division to maintain volunteers and keep them motivated. My expectation is that we find more passionate volunteers who love to spread the word of quality and compliance through conferences, discussion groups, and section meetings.

Through our members, we can find these passionate individuals. I know your time is valuable, and I appreciate your willingness to assist. For our division to ensure its ability to continue delivering all the value that the division has to offer to our members, we need these same members to be volunteers—to help us give back.

So I call on volunteers to help the division achieve its goals and continue to give back to the division's members. Contact any of the officers. See the officer listing in the website or contact Nora Dowell at nora.dowell@ivcinc.com.

Thank you to all who have helped us as a division—new and old participants. I recognize we cannot be successful without the contributions made by each and every one our members.

Cathelene Compton
2015 FD&C Division Chair
cathelenecompton@yahoo.com

EVENTS: 2015

The ASQ Food, Drug, and Cosmetic Division

2015 Northeast Conference and Its Successful Outcome

The ASQ Food, Drug, and Cosmetic (FD&C) Division and the ASQ Princeton Section 307, Northeast Conference 2015 held at the Johnson & Johnson Corporate building in New Brunswick, NJ on April 10 – 11, 2015, was a resounding success. The event, including the opportunity to take part in one of two certification examinations, attracted experienced professionals in the food, medical device, and pharmaceutical industries, and local graduates from Rutgers University.

I am pleased to announce that for the first time in our continuing effort to provide and support valuable opportunities for learning, networking, and knowledge exchange to increase the use and impact of quality in response to the diverse needs of the world, we presented the Pharmaceutical GMP Professional (CPGP) and the HACCP Auditor (CHA) intensive full-day workshops, followed by the certification examinations the next day for applicable pre-registrants.

The conference attendees learned key information from dynamic leaders in business practice. We are thankful and honored for the excellent learning opportunity provided by: the CPGP workshop instructor, Mark Durivage, and the HACCP workshop instructor, Aura Stewart. ASQ's CPGP and CHA certifications are the preeminent certifications of the ASQ FD&C Division, which focuses on quality and safety in the workplace, supply chain, marketplace, and humanity worldwide.

Special acknowledgement to: Scott Schell, director, compliance; Bill Cope, senior director, compliance; and Paul Edson, vice president regulatory compliance at Johnson & Johnson Corporate for believing in us and our mission of making these workshops and certification examinations available to many interested quality professionals. We are thankful to countless leaders in quality to jointly continue to raise the voice of quality. The ASQ FD&C Division and the ASQ Princeton Section 307 are dedicated to serving and advancing the cause of quality in every segment of our global community.

An amazing lineup of conference partners, stakeholders, and supporters contributed to the success of the ASQ FD&C Division and ASQ Princeton Section 307 2015 Northeast Conference: Rosemarie Christopher, FD&C membership chair/past chair; Belinda Beardt, executive assistant to Rosemarie Christopher; Milton Matamoros, FD&C Northeast Conference chair/Princeton Section 307 programs chair; John Reynolds, CHA, and Luke T. Foo, CPGP, region 3B/co-counselors; Scott Schell, liaison at Johnson & Johnson; Mark Durivage, CPGP workshop instructor; Aura Stewart, HACCP/CHA workshop instructor; Mary Martin, ASQ administrator, Certification Offerings; Cathelene Compton, FD&C chair; Bernie Klemmer, Princeton Section 307 chair; Lynn Hamilton, Liliana Matamoros, and Chiniqua Garcia, Princeton Section 307 program and logistics team; Jill Vila, Princeton Section 307 proctor chair; and Anne Pericone and Cynthia Rooney, Princeton Section proctors.

Milton Matamoros
FD&C NE Conference Chair/
Princeton Section 307 Program Chair
Milton.Matamoros@asqprinceton.org
609-576-4900

2015 Northeast Conference

Aura Stewart, Lynn Hamilton, Luke Foo, Scott Schell, Mark Durivage, Liliana Matamoros, Chiniqua Garcia, Milton Matamoros

COMMODITY OR CONTRIBUTOR?

STEM workers must be prepared for "the project economy"

Rosemarie Christopher

According to Gallup, 70 percent of us are disengaged at work, costing U.S. organizations half a trillion (not a typo) dollars a year.[1]

If you are reading this column, you are most likely one of the 30 percent of U.S. workers who are proactively engaged in their work. You are the one who will be retained and promoted by your employer, or you are the one actively recruited by former bosses or in-house or agency recruiters. Odds are, you are not looking to make a job change. This column is addressed to you, because while you are busy making the bottom line of your organization robust, there are forces that will ultimately catch up with you.

77.8 percent of employers participating in the National Association of Colleges and Employers Job Outlook 2015 survey chose leadership and the ability to work in a team structure as the main attributes

Being unprepared for what is being called "the project economy"—with its project-by-project work and just-in-time hiring—could radically affect your career progress. These changes are the result of rapidly maturing global markets, exploding technology, pressures of volatility in the economy, and the impact of having almost five generations in the workforce. Three of these generations are demanding and will continue to demand adjustments and new work delivery formats that reflect movement from outdated industrial-age, hierarchical work models to ones that reflect, adjust to, and respect the new project economy's knowledge workers.

The project economy

Pieces of the perfect storm that led to the new project economy include:

- A stubbornly stagnant economy since 2008, which is finally showing signs of recovery
- C-suite pressure to comply with competitive market demands with far fewer human resources
- General corporate inability to manage a science, technology, engineering, and mathematics (STEM) talent shortage
- Globalization
- The cost of full-time equivalency (FTE) employment created by the Affordable Care Act, 401K plans, and pension plans
- High-tech, work-anywhere 24/7 employment models made possible by technology

What is the project economy?

In this new project economy, face time is overrated. Flex time and flex place are attractive to knowledge workers because just-in-time hiring and project-by-project work make complete sense to them. At the same time, there is a not-so-obvious but real effort on the part of some entities to commoditize STEM professionals. The result of making professional knowledge workers mere commodities will exert downward pressure on wages and cause subsequent shrinking of the middle class.

All these factors offer knowledge workers a brand new way to be engaged, work fairly independently, enjoy a high quality of life, and add significant value through increased creative productivity. What is important for knowledge workers of the 21st century is to use creative consciousness to plan their careers.

Leadership and teamwork

Regardless of whether you work in a bricks and mortar establishment or work remotely as an FTE, contract worker, or consultant, 77.8 percent of employers participating in the National Association of Colleges and Employers Job Outlook 2015 survey chose leadership and the ability to work in a team structure as the main attributes they look for most in a candidate's résumé.[2]

This is not surprising when considering more flat organizational structures, project-by-project work assignments, and generational differences in work style—all characteristics of the project economy. FTE, part-time, and contract STEM-educated and experienced professionals are key to the success of any project, not because of their job titles or seniority but because more can be expected of tech-savvy subject matter experts holding higher-skills jobs.

So the takeaways for knowledge workers in the new project economy are that they must consciously and continuously improve their career plan trajectories so that, one professional at a time, they prevent themselves and their profession from being commoditized.

Today's desirable attributes

In résumés or in references, whether they work as FTEs or as contracted remote workers, bosses, peers, direct

reports, or clients can count them among the 30 percent of engaged workers for having the following attributes:

- **Is a critical thinker:** streamlines work; is an active contributor to problem solving.
- **Is proactive:** determines how the project or task at hand fits into the bigger picture.
- **Is a confident communicator:** checks in with peers and teammates often, regardless of whether that is a preferred work style.
- **Is accountable:** earns the department's and organization's trust, and that trust is returned by the department and organization.
- **Shows good judgment:** values compliance, but is not afraid of disruption when change is necessary.
- **Possesses work-life balance:** respects their own and others' quality of life and knows taking time off and pacing can unleash real creativity and productivity in oneself and others.
- **Demonstrates a positive attitude:** understands what is meant by servant leadership; expresses gratitude for the opportunity to contribute and work with talented team members.
- **Listens:** being present to others means being open, flexible, approachable, and willing to really hear others.

We have reached the enviable position where an engaged knowledge worker who builds relationships based on trust can have a meaningful impact on his or her career progression while simultaneously inspiring project teammates to swell the ranks of the 30 percent of engaged workers.

REFERENCES

1. Gallup, *State of the American Workplace Report 2014*, www.gallup.com/services/178514/state-american-workplace.aspx.
2. National Association of Colleges and Employers, *Job Outlook 2015*, www.naceweb.org/surveys/job-outlook.aspx.

About the Author:
Rosemarie Christopher is an organizational communications consultant and the president and CEO of MEIRxRS, a family of science, technology, engineering, and math recruitment and staffing organizations in Glendale, CA. Christopher also consults organizations on effective communication within their workforce. She has a master's degree in communication management from the University of Southern California in Los Angeles, CA. Christopher is an ASQ member and chair of the ASQ Food, Drug, and Cosmetic Division.

Call for Content to Publish in the FD&C Division Newsletter

Please contribute an article for the newsletter that is informative, beneficial to members, enhances knowledge base or industry practices, and helps in research and development.

Suggested topics may include:

- Technical field
- Good practices in workplace/experience worth sharing
- Quality aspect
- Regulatory affairs/update
- Member achievements/ outstanding contribution
- Industry news
- Member suggestions/ thoughts

Please submit content (including articles) for potential publication in one of three newsletters published annually.

Arvind Badkas, FD&C Division Newsletter Editor
abadkas@gmail.com

Risk Assessments for Pharmaceutical Excipients

Luke Foo, NJ Regional Counselor
for the FD&C Division of ASQ

On March 21, 2015, the guidelines on formalized risk assessment for ascertaining the appropriate good manufacturing processes (GMPs) for excipients used in drug products for human use was published in the Official Journal of the European Union. The new guidelines are now part of the EU GMP guidelines under Part III of EurdraLex Volume 4 GMP Guidelines. The risk assessment should take into account the source (animal, vegetable, mineral, or synthetic), the intended use, and previous quality defects of the excipient being assessed, and apply the GMPs that are appropriate for that excipient.

This guideline does not apply to veterinary drug products, active pharmaceutical ingredients (APIs), packaging materials, and substances that are added to stabilize active substances that cannot exist on their own.

The risk assessment tools to be used may include, but are not limited to, those tools found in ICH Q9.

Areas of consideration for risk assessment include:

1. Transmissible spongiform encephalopathy
2. Potential for viral contamination
3. Potential for microbiological or endotoxin contamination
4. Potential for any impurity originating from the raw material
5. Sterility assurance for excipients claimed to be sterile
6. Environmental control during storage and transportation
7. Supply chain complexity
8. Packaging integrity evidence

The degree of risk (low, medium, or high) should take into consideration:

1. The pharmaceutical form and use of the finished drug product
2. The function of the excipient
3. The proportion of the excipient in the drug product composition
4. The daily patient intake of the excipient
5. Any known quality defects or adulterations
6. Known or potential impact on the critical quality attributes of the drug product
7. Factors that would impact patient safety

The guideline recommends the following high-level GMP elements by the supplier:

1. Establishment of an effective pharmaceutical quality system
2. Sufficient competent qualified personnel
3. Defined job descriptions
4. Training program
5. Maintenance of facilities and equipment
6. Documentation systems for processes and specifications
7. Coding systems to allow for traceability of starting materials, intermediates, and excipients
8. Supplier qualification program
9. QC testing and release procedures
10. Record retention system
11. Written contracts with CMOs
12. Complaint and recall procedures
13. Change management and deviation management systems
14. Self-inspections
15. Environmental controls for storage and handling

The guideline suggests performing a gap analysis during an audit of the excipient supplier. Any gaps identified should be documented.

Once the appropriate GMPs and the risk profile of the excipient manufacturer have been defined, ongoing risk reviews should be performed. This may be achieved by monitoring and trend analysis, re-audits, questionnaires, or review of status of GMP certification of the supplier.

This guideline goes into effect on March 21, 2016.

SCIENCE AND COMPLIANCE: THE RIGHT RECIPE FOR PAI SUCCESS

Edward R. Arling

A pre-approval inspection (PAI) of a pharmaceutical or biopharmaceutical product is equivalent to graduation day for all those working toward a new drug approval. That includes the scientists, engineers, patient volunteers, marketers, production, quality, and other support staff. It is the final hurdle to clear after several years of discovery, clinical and manufacturing development, and pulling all the data together into a regulatory submission. Company executives, employees, vendors, contractors, and shareholders all hold their breath and wait for the outcome of the PAI to either rejoice in approval or watch as the company begins remediation efforts to correct discovered deficiencies (and their reputation) while the product is withheld from the market.

Ensuring success of the PAI should be one of the main areas of focus during the last stages of development. A two-year or longer preparation strategy, prior to submission, is required by an expert team to ensure a high degree of success during the PAI. Many companies fail to put in the time or expertise to ensure the PAI goes as smoothly as desired. Starting work on your PAI readiness after the submission has been accepted is very late in this high-stakes game to ensure success or remediation of critical inspection focused areas.

Over the years, many promising molecules and excellent science, on their way to regulatory approval, have become derailed due to poor compliance practices. Typically, reviewers for new drugs are science based and much of what leads up to the PAI is a review of the safety and efficacy of the molecule. This review is performed off site, in the reviewer's office, with little exposure to the facility where the product will be manufactured. Once safety and efficacy issues have been reviewed and accepted, the next step is the scheduling of the on-site inspection. The on-site inspection may include a visit by the reviewer, who is primarily looking at the science, but will always include field investigators whose primary interest is the compliance aspect of the facility, personnel, and management. Expect on-site PAI inspections to occur at the active pharmaceutical ingredient (API) site of manufacture, final dosage form sites, packaging sites, testing facilities, and even at warehouse and distribution facilities.

On-site inspections will typically consist of a team of investigators, perhaps consisting of validation experts (computer and manufacturing, microbiologists, chemists, compliance experts, and/or other relative expertise). The on-site PAI compliance team will be interested in two primary areas: the validity of the data included in the submission the company made to the regulatory body and the supporting quality system that supports the product submitted.

The PAI aspects of the inspection are part of the FDA inspection manual CP 7346.832. The FDA uses a quality systems inspection technique (QSIT) for conducting inspections that evaluate the firm's quality system. The process is described in the Compliance Program Guidance Manual, number 7356.002. The six areas to be covered during the PAI include: quality, facilities and equipment, materials, production, laboratory controls, and packaging and labeling. This means that the company's entire quality system is fair game for review and examination during the PAI inspection.

The FDA will be evaluating the quality system in relation to both the product submitted for approval and other products the firm manufactures. A poorly managed deficiency noted in the deviation process (even for an unrelated product), during an inspection, will be a reflection of the company's behavior and quality system strength and robustness. Several observed minor deficiencies could result in a negative impression on how the PAI team views the product being applied for approval.

Key areas that will be reviewed during the PAI are the quality unit, including management, change control, deviation investigation, documentation, nonconformance practices, out of specification (OOS) management review, and follow-up and data integrity. Oftentimes unresolved or long cycle times for closure of nonconformances, change controls, and deviation investigations are symptomatic of a weak quality unit.

One common mistake many companies make is to address a deviation or OOS during internal meetings and discuss the science behind the issue. Impact to operations, safety, and other considerations are discussed, but the findings, corrections, or actions taken are not adequately or properly documented per the company procedure or regulatory expectation. They miss the point of following their compliance procedures. The science supports the product, but the compliance is lacking. Both are necessary to be successful during the PAI for the submitted product and all other products that may come under scrutiny during the PAI inspection.

Planning early, and using the right expertise to facilitate readiness should ensure a successful PAI and help get that new product to market. Always ensure that any scientific rationale or justification applied to compliance decisions is adequately documented and rationale or justification is substantiated. Using good science and doing it in compliance is the key to PAI success.

About the Author:
Edward Arling is the principal of Quality Compliance Associates, LLC and immediate past chair of the ASQ Food, Drug, and Cosmetic Division. He can be contacted at edward.arling@gmail.com.

STOP SABOTAGING YOUR COMPANY

Carrie Van Daele

My phone wasn't working, so I got in touch with my phone-line provider. Two technicians came to my house expecting to fix my line, but they worked for more than an hour until they admitted they had no idea how to correct the problem. These technicians were maybe 25 years old. I heard one of them say, "Let's call Hank."

"Who's Hank?" I asked.

"Hank knows everything about phone lines because he's worked here for over 35 years, and he's gonna retire this year," said one of the technicians.

Hank described the problem and the solution to the technicians, and my phone line was repaired shortly thereafter. "We're kinda nervous about our job when Hank retires because we don't know as much as he does," said the technicians. This happened in 2009.

Where was your lean/quality focus in 2009 during the economic downturn? Did you witness your organization doing little to retain its tribal knowledge from people like Hank, only to end up with a skills gap in 2015?

Where is your lean focus now? It's not enough for you to focus on correction, overproduction, motion, material handling, waiting, inventory, and processing without also addressing the skills gap. To grow market share, production, and revenue in 2015, you will need to stop sabotaging your organization by being fashionably lean, yet ignoring ways to maximize and capitalize on your workforce, especially with people like Hank.

Your supply chain includes people, time, equipment, space, and money, all dedicated to moving a product or service from supplier to customer. If you don't fill the skills gap, that becomes a missing link in your supply chain—a bottleneck choking off your pace for process improvements, defect prevention, and reduction of variation and waste.

Joe Genc is a tool engineer with 56 years of shop-floor experience, including 25 years as an educator. At age 70, Genc is working to close the skills gap at Berry Plastics and in his industry as a moldmaking instructor for the Technology & Manufacturing Association (TMA). Both are using Genc's extensive knowledge to train younger workers.

Who are your 20-percenters?

Perhaps 80 percent of your workforce skills are owned by 20 percent of your workforce. But do you know who those 20 percent are and how to maximize and capitalize on their knowledge?

To fill the skills gap, you must first consider your workforce as an asset, not a liability. Calculate the valuation of your workforce in earnings and financial asset returns, instead of labeling your workforce an expense. Ask two questions about each employee: "What future earnings can Bob bring to my organization?" and "How can I better utilize Mary?" Your answers will help you to achieve marginal benefit from your workforce, which means your organization will net a greater return on investment from each employee.

Marginal benefit is a micro-economic term used to describe how to increase people, time, equipment, space, and money in a company without adding any cost to the bottom line. One aspect of marginal benefit is about leveraging the 20 percent of your workforce—training them, upgrading their skills, and utilizing their knowledge to the fullest to benefit your organization. Genc is a perfect example of how Berry Plastics leveraged an employee's tribal knowledge both on the job and in the classroom to build and strengthen the talent pipeline for more growth at the company (and in the plastics industry in general).

Has your gap analysis identified areas where your workforce is performing below the standards expected by your customers, industry, and management? Are these shortcomings compromising the competitiveness of your organization? Wasting tribal knowledge is damaging to your organization's success.

Instead of waiting for schools to fill the skills gap, many companies are creating their own training programs utilizing their in-house trainers and subject matter experts (SMEs) as instructors. These programs include job shadowing, apprenticeships, internships, mentoring, and more.

How it works

If your organization is running at a 70-percent capacity utilization rate, it has room to increase production up to 100 percent without increasing costs. In other words, your production is underutilized. Correct? In the same way, you can also underutilize the tribal knowledge of your workforce.

You will need to champion marginal benefit by learning more about your 80/20 workforce. First, identify your trainers and/or SMEs (people like Joe Genc) and capitalize on their tribal knowledge to determine where they can have the greatest effect at your organization.

Answer these capacity-utilization questions about your trainers and SMEs to determine how you will achieve 100-percent output levels from your workforce:

1. Who are my trainers/SMEs?
   Hank, the phone technician, and Joe, the tool engineer
2. How are my trainers/SMEs capitalized and utilized?
   Both Hank and Joe, as instructors
3. How are my trainers/SMEs integrated in lean and other training?
   On the job
4. How are my trainers/SMEs improving operating performance?
   By developing people
5. How are my trainers/SMEs trained?
   By following a train-the-trainer system

Give your trainers and SMEs a system to follow for a consistent standard work. Richard White, manager at Honda New Model and Quality Planning, shared his thoughts on this. "Experience alone does not make a good trainer or SME," he says. "Individuals must be trained and qualified to achieve standard work from their learners."

White also identified some common pitfalls with experienced trainers/SMEs who have no formal training system. They:

- Forget what it's like to learn the job
- Have too many assumptions
- Gloss over details
- Have poor communication skills
- Teach from memory and not the standard
- Lack the desire to teach or train

Training mustn't include inconsistent, offhand, approximations

Too many trainers and SMEs randomly train on the job without training objectives or a document that outlines the standard work to follow. Without a formal training system for trainers to follow, the safest, highest-quality and most efficient way to perform a standard task or process is compromised. Ask yourself:

1. Do your trainers/SMEs use a formal training system?
2. Do your trainers/SMEs know how to prepare, present, practice, and follow up?
3. Do your trainers/SMEs know the best training methods to use?
4. Do your trainers/SMEs know how to train on the job?
5. Do your trainers/SMEs know how to train in the classroom?
6. Do your trainers/SMEs know how to explain a concept and teach lean practices?
7. Do your trainers/SMEs know how to handle frustrated learners?

A four-step method

A formal training system for your trainers and SMEs should include a four-step training methodology:

1. **Preparation:** Identify the gaps in current standard work and improvements for standard work.
2. **Presentation:** Explain and demonstrate the standard work required.
3. **Practice:** Use a variety of training methods for employees to meet standard work required.
4. **Evaluation:** Determine improvements of standard work from employees.

Identify your trainers and SMEs and certify them to follow a formal training system.

In summary, you must forge a partnership with human resources and your workforce to fill the skills gap. It is no longer simply the human resource department's responsibility. You must now formulate lean/quality strategies that capitalize and maximize the 20 percent of your workforce to build products and services that customers demand.

Where is your focus?

Take a final moment to answer the questions below to determine where your focus is, and then make a commitment to filling the skills gap in 2015:

- Do you know the 20-percent tribal knowledge workforce?
- Are you utilizing the 80-percent tribal knowledge at 100-percent capacity?
- Are your trainers/SMEs certified to a training system?

Go back to the basics. Contact your human resource group today to learn more about your workforce's competencies, expertise, education, and experience so you can align your 2015 lean initiatives to maximize and capitalize on the knowledge from your workforce.

About The Author

Carrie Van Daele is president and CEO of Van Daele & Associates Inc. at www.leant3.com, featuring her Train the Trainer System for trainers and subject matter experts. Van Daele's company was founded in 1993 as a training and development firm in the areas of leadership, train the trainer, continuous process improvements, team building, strategic planning, sales/marketing, workforce development, and general business consulting. Van Daele is the author of *50 One-Minute Tips for Trainers* published by Logical Operations.

WHERE IS THE "QUALITY" IN GCP?

Suzanne Tran

Over the years, clinical study management has become more fragmented. There are more organizations participating in a study, each bringing their own experiences and interpretations of requirements including how quality is defined. How is it possible that requirements and quality be interpreted so differently?

To start, the Code of Federal Regulations (CFR) items pertaining to good clinical practices (GCPs) do not mention the term "quality" directly. Any reference to the use of "quality" is typically associated with an attribute. For example, in 21 CFR 312, it refers to quality in terms of "scientific quality" and "quality" of the drug substance, whereas the term "quality" on its own is used in numerous parts of 21 CFR 58 *(Good Laboratory Practice for Nonclinical Laboratory Studies)*: Part 38 alone addresses the requirement for a quality assurance unit (QAU) to monitor nonclinical studies.

Quality practices as they relate to GCPs are more visible in the *Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (1996)*. The introduction states, "This guidance should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities." Since quality control and quality assurance are not mentioned directly in the CFRs but in guidance such as ICH E6, does this mean that quality is not important in GCPs? No.

Essentially, quality involves a set of principles/practices an organization uses to verify that requirements are being fulfilled. Applicable standards, regulations, and customer requirements as well as guidance and industry-wide practices comprise "requirements" to be fulfilled.

Despite the role an organization has in GCPs, there is need for the requirements to be clearly established and controlled systematically throughout the clinical study. Why? A study is only as strong as the weakest participating group. Essentially, a process is an activity or group of activities that takes an input, adds value through the use of resources, and provides an output to internal and/or external customers. The value added by a process comes in exchange for the resources it uses, including people, equipment, material, money, and time. For example, if site monitoring is not a well-defined activity and is performed without proper oversight, the weakest organization has the potential to introduce more variation in the execution of the study protocol and thus potentially compromise the study results.

It should be noted that relying on one area of quality, such as quality control activities, is not enough. At a minimum, there is a need for both quality control and quality assurance activities. As defined in ICH E6:

- **Quality Control (QC):** The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.
- **Quality Assurance (QA):** All of those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCPs and applicable regulatory requirement(s).

In other words, QC includes many activities (operational techniques) to ensure that a protocol is being followed, such as with clinical site monitoring and the establishment of an investigational review board (IRB). QA includes the actions taken to ensure that the activity is conducted effectively and efficiently. It encompasses the use of established practices that include, but are not limited to: management commitment, written standard operating procedures (SOPs), audit reports, computer system validations, and training records.

To aid in controlling process variation, a well-established process approach should be used throughout the study and understood as well as practiced by all participating organizations. This practice breaks down the life-cycle activities in terms of smaller interrelated processes. It also maintains focus on how the quality of one process affects the quality of the next.

As with the difference between QC and QA, there is a difference between what demonstrates a quality system and a quality management system. A quality system typically focuses on a few areas of quality practices (techniques), such as written SOPs, while a quality management system is more comprehensive. Quality management is focused not only on product and service quality, but also on the means to achieve it. Quality management therefore uses QA and control of processes to achieve more consistent quality.

A good model for establishing a quality management system is the ISO 9001 standard. Developed and published by the International Organization for Standardization (www.iso.org), an international standards writing body, ISO 9001 standard is a set of requirements. The ISO 9001 requirements reflect time-proven, universally accepted business practices. This standard is probably the best known international standard for quality management.

What does ISO 9001 demonstrate? By implementing the requirements, the organization is capable of demonstrating that: (1) it has the ability to consistently provide products or services that meet customer and applicable statutory and regulatory requirements; and (2) the organization aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

In general, the ISO 9001 requirements address the following:

- Implementing structure by establishing a quality management system
- Establishing responsibilities by involving top management
- Providing resources to achieve goals through resource management
- Designing and performing to requirements (such as customer, statutory, regulatory)
- Raising the bar by measurement, analysis, and improvement activities

The quality, not just compliance, in GCPs therefore comes from organizations that collaborate in conducting a clinical trial that protects human subjects and meets the applicable statutory and regulatory requirements, as well as proactively improve the use of resources to gain regulatory approval in a timely manner so that others may reap the benefits of the new therapy.

About the Author:
Suzanne Tran is a QA compliance specialist for Technical Resources International (TRI). She has more than 20 years of experience in the quality field. She is an ASQ Senior member and an ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE), Quality Auditor (CQA), and Software Quality Engineer (CSQE).

2015 FDC Division Regional Counselors

Region 1
Charles Schell
schellshocked@aol.com

Region 2
Alan Brust
Alan.Brust@ge.com

Region 3A
James Goldstein
jamesgoldstein@imsm.com

Region 3B/Co-Counselor
John Reynolds
Jreyn8080@yahoo.com

Region 3B/Co-Counselor
Lfoo6952@mac.com

Region 4
Andrew Gould
cmag@sympatico.ca

Region 5B
Donald C. Singer
donald.c.singer@gsk.com

Region 6A
Seiha Buth
Seiha.buth@gmail.com

Region 6B
Sophia Hernandez
Sofia.hernandez@boehringer-ingelheim.com

Region 7A
Mary D. Thorsness
mthorsness@aol.com

Region 7B
Nora Abanez Dowell
noraa@ivcinc.com

Region 8
Danita Thomas
danita_thomas@steris.com

Region 9
Katherine Gilson
kgilson@twc.com

Region 10
Dean Basinger
Dean.basinger@pinnaclefoods.com

Region 11
Dennis Hannigan
dennishannigan@gmail.com

Region 12
Sandra R. Storli
storli4600@sbcglobal.net

Region 13
Ross Jabaay
Ross.jabaay@gmail.com

Region 14
Timothy P. Parrent
tim.parrent@mkcorp.com

Region 15
Kirk Brown
Kirk.brown@noaa.gov

Latin America
Aura Stewart
Aura.stewart@outlook.com

2015 FDC Division Leaders

Chair
Cathelene Compton
cathelenecompton@yahoo.com

Chair-Elect
Nancy Berger
nancy.berger@eagleregistrations.com

Vice Chair
Elena Mack
Elena.Mack@westpharma.com

Treasurer
William J. Taraszewski
william.taraszewski@meda.us

Secretary/PAR Chair
Lisa A. El-Shall
lisa.el-shall@pfizer.com

Membership Chair/Past Chair
Rosemarie E. Christopher
christoroseasq@gmail.com

Immediate Past Chair/ Nominating Chair
Edward R. Arling
edward.arling@gmail.com

Co-Author Toolbox
Mary D. Thorsness
mthorsness@aol.com

Awards Coordinator
Akiko Tagawa
info@qualityfacts.com

Canada/Breakfast Conference Chair
Andrew Gould
cmag@sympatico.ca

Certification Chair
Donald C. Singer
donald.c.singer@gsk.com

CHA Chair
Todd Jacobs
todd.jacobs@sensient.com

Communications Chair/ Newsletter Editor
Arvind Badkas
abadkas@gmail.com

HACCP Standards Committee Chairs
John Surak
jgsurak@yahoo.com

Steven Wilson
steven.wilson@noaa.gov

Long Island Conference Chair BioMed Research Standard Chair
Rick Calabrese
rick.calabrese@sartorius.com

Northeast Conference Chair
Milton Matamoros
miltonmm2@gmail.com

Southeast Conference Chair
rick.perlman.b@bayer.com

West Coast Conference Chair
Rosemarie E. Christopher
christoroseasq@gmail.com

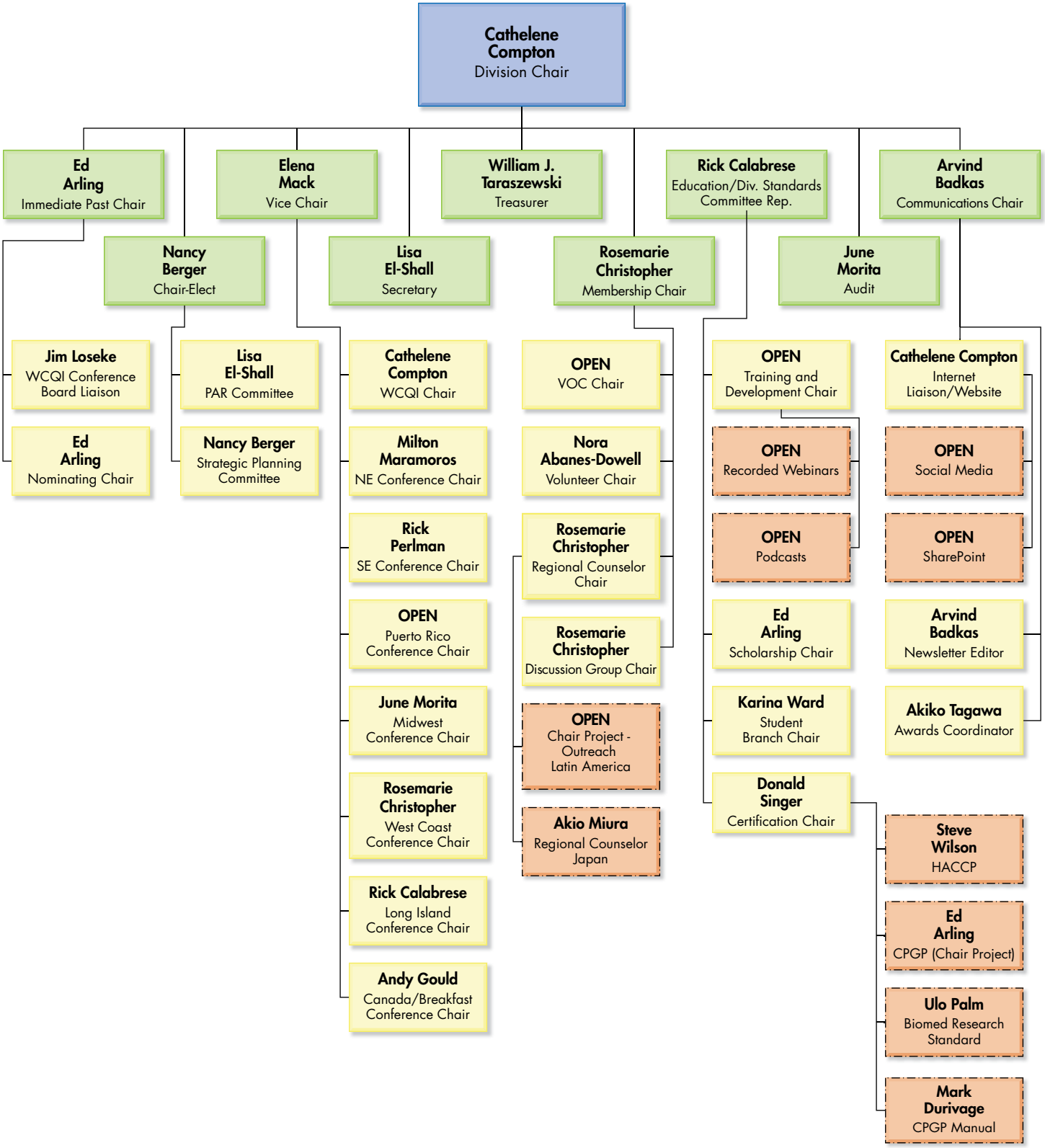
Midwest Conference Chair/ Budget Audit Chair
June M. Morita
moritaj@wowway.com

Scholarship Chair
Kanti Thirumoorthy, PhD
kantit@roadrunner.com

Volunteer Chair
Alice Krumenaker
a.krumenaker@gmail.com

WCQI Conference Board Liaison
Jim Loseke

Regional Counselor Chair
Rick Calabrese
rick.calabrese@sartorius.com


Cathelene Compton
Division Chair
Ed Arling
Immediate Past Chair
Elena Mack
Vice Chair
William J. Taraszewski
Treasurer
Rick Calabrese
Education/Div. Standards Committee Rep.
Arvind Badkas
Communications Chair
Nancy Berger
Chair-Elect
Lisa El-Shall
Secretary
Rosemarie Christopher
Membership Chair
June Morita
Audit
Jim Loseke
WCQI Conference Board Liaison
Ed Arling
Nominating Chair
Lisa El-Shall
PAR Committee
Nancy Berger
Strategic Planning Committee
Cathelene Compton
WCQI Chair
Milton Maramoros
NE Conference Chair
Rick Perlman
SE Conference Chair
OPEN
Puerto Rico Conference Chair
June Morita
Midwest Conference Chair
Rosemarie Christopher
West Coast Conference Chair
Rick Calabrese
Long Island Conference Chair
Andy Gould
Canada/Breakfast Conference Chair
OPEN
VOC Chair
Nora Abanes-Dowell
Volunteer Chair
Rosemarie Christopher
Regional Counselor Chair
Rosemarie Christopher
Discussion Group Chair
OPEN
Chair Project - Outreach Latin America
Akio Miura
Regional Counselor Japan
OPEN
Training and Development Chair
OPEN
Recorded Webinars
OPEN
Podcasts
Ed Arling
Scholarship Chair
Karina Ward
Student Branch Chair
Donald Singer
Certification Chair
Steve Wilson
HACCP
Ed Arling
CPGP (Chair Project)
Ulo Palm
Biomed Research Standard
Mark Durivage
CPGP Manual
Cathelene Compton
Internet Liaison/Website
OPEN
Social Media
OPEN
SharePoint
Arvind Badkas
Newsletter Editor
Akiko Tagawa
Awards Coordinator