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

GLOBAL VIEW

May 2014 No. 173

CHAIR'S MESSAGE

by Edward Arling

As we begin 2014, I would like to welcome all our new Food, Drug, and Cosmetic (FD&C) Division members and reconnect with all our current members who have been part of the division over the past and help make our division strong and successful.

Division Status

- The FD&C Division is financially healthy and our membership remains strong. We currently have sufficient funds and investment reserves to fund our 2014 planned projects including three planned conferences, webinars, section-sponsored breakfast meetings, and focused discussion groups. We also plan to maintain and improve our two division certifications—Pharmaceutical GMP Professional (CPGP) and HACCP Auditor (HCA)—and our presence at and support of the World Conference on Quality and Improvement in Dallas, TX, in May. Our current membership is just over 4,500 active full-time members.

Member Value

- The FD&C member leaders met in October to design our business plan for 2014. Our central theme and focus was creating and delivering member value. Our 2014 business plan is available to all members on our Sharepoint site at https://share.asq.org/help/_layouts/15/start.aspx#/SitePages/Home.aspx. Key areas of focus include: delivering value-added webinars, webex sessions, and conferences to our members; completing ongoing work on the *CPGP Reference Manual*; sponsoring a two-day seminar at Disney for food safety; and improving member communication through upgrading our means of communication.

Call for Volunteers

- ASQ is a volunteer, nonprofit organization supported by and driven by quality professionals who are passionate about quality. The FD&C Division is fortunate to have dedicated member leaders and volunteers driven to improve quality and provide member value. The division is ALWAYS looking for more support from our 4,500 members to assist with our planning, program development, and the many areas where the division is bringing value to members, primarily through our education and knowledge-sharing efforts. Please take a minute to review our 2014 goals, get involved, contact our volunteer chair, provide your input, and make a difference. We currently have need for members interested in helping us complete our CPGP efforts and anybody interested in assisting in our newsletter, social media, and/or website communication efforts with our members.

Wishing everyone a safe and prosperous 2014!

Edward Arling
2014 FD&C Division Chair
edward.arling@gmail.com

Call for Articles!

Interested in writing an article for the newsletter?

Submission deadlines are the 15th of each month. Please contact **Arvind Badkas (arvind_badkas@yahoo.com)** for further information.

Editor: Arvind Bodkas

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.

Planned Member Value Activities

World Conference on Quality and Improvement

Visit the link for details:

http://wcqi.asq.org/?WT.dcsvid=OTIwMTYwMDk4MDcS1&WT.mc_id=EM1111419

Quality and Safety Conference

June 11 Preconference Workshop
EARLY-BIRD RATE = $200 member/$350 nonmember

- Hazard Analysis and Critical Control Points (HACCP)
  Refresher Course/CHA Exam Preparation

June 12 – 13 Quality and Safety Conference
EARLY-BIRD RATE = $350 member/$500 nonmember

- Food Safety Modernization Act (FSMA)
- Good Manufacturing Practice (GMP)
- Good Lab Practice (GLP)

For more information, please visit

http://qualityandsafetyconference.com

Quality and safety professionals at all levels and from companies of all sizes are invited to learn immediate actionable solutions for program improvements and solve tough challenges in today's workplace at the Quality and Safety Conference.

2014 FD&C Division Goals

PAR: Three Letters to Know

by Chris Allen, PAR Committee

Starting in 2014, ASQ is changing the way sections and divisions do their annual planning. What previously was called the "QMP Program" is now Performance Awards and Recognition (PAR). Why the change? QMP stood for quality management plan. Each year the division officers developed a business plan for the coming year, submitted it to HQ, and tracked compliance to the plan monthly. While the QMP included many member-related activities like seminars, workshops, and publications, it was also very focused on compliance with the management agreement the division had with HQ. PAR has been designed to focus more keenly on the drivers of member satisfaction, loyalty, and engagement. For example, one big driver of member value creation will be the new requirement for divisions to create positive experiences for members and to spend 70 percent or more of annual revenues on "value" activities such as meetings, dinners, training, certification, and networking events.

Members of the FD&C management team met this past October to develop the 2014 PAR. The result is an ambitious but exciting document that outlines this year's goals for making the division more valuable to all our members. Included in the document are nine main objectives. These include developing a new member communication plan, holding a major food quality and safety conference, developing new technical webinars, completing a "toolkit" training program for our member leaders, completing the *Certified Pharmaceutical GMP Professional Handbook*, and developing a global outreach program. More information can be found in the document, and the PAR plan will be posted on the FD&C website for your review early this year. You will be hearing more about the specific activities and events in upcoming newsletters and email notices.

The FD&C-PAR is a big plan and it will certainly require a big commitment from all of us to make it happen. We will be keeping you informed throughout the year and are looking forward to your feedback and involvement.

2014 Business Planning Meeting, October 2013

2014 FOOD, DRUG, AND COSMETIC LEADERSHIP TEAM

Rosemarie Christopher (Past Chair 2012-2013, Membership Chair)

Eduardo Heidelberg (FDC Div. Past Chair)

Nancy Berger (Vice Chair)

Arvind Badkas (Communication Chair)

FD&C Division Slate of Officers

January 1, 2014 – December 31, 2014

Dear Food, Drug, and Cosmetic Division members,

Per our division management agreement (DMA), our call for nominees for the elected positions of the division that consist of the chair, chair-elect, treasurer, and secretary positions was announced on our website and via email in October 2013. No nominations from the general membership were received and therefore, under Section 6.2 of our DMA, if there is not more than one nominee for an elected position, the nominee shall be declared elected by acclamation at the next regular meeting of the Division Management Committee.

The following nominees have been declared as being elected for the 2014 calendar year:

Chair	Ed Arling
Chair-Elect	Cathelene Compton
Vice Chair	Nancy Berger
Treasurer	Mariangeli Diaz Salgado
Secretary	Niedre Heckman

Mariangeli Diaz Salgado, our new treasurer, is a quality management professional with 15 years in project management—primarily in the pharmaceutical industry. She has worked with various companies and clients throughout Puerto Rico, Santo Domingo, and Mexico as well as in the United States. Her experience includes working with various remediation projects as well as working for major pharmaceutical companies in various quality assurance and management roles. We welcome her experience and global perspective to the Executive Committee of the division.

Rosemarie Christopher, current chair of the division and soon to be past chair, will assume the role of the chair of the Nominating Committee in 2014. If you would like to nominate yourself or another qualified member for any of these positions for the 2015 calendar year, you can get further information from either Rosemarie, me, or any other Executive Committee member. Position descriptions are available on the ASQ website for each of the elected positions and many of the appointed positions. Generally, nominations will be requested from the general membership in October each year. Should we receive nominations, an election will be held. We welcome any/all interested parties as we help to shape our future through our activites to add ongoing value for our members.

Jim Loseke
Immediate Past Chair,
Food, Drug, and Cosmetic Division
Nominating Committee Chairperson

CPGP Handbook Reaches Major Milestone

by Mark Durivage, CPGP Chair

The Certified Pharmaceutical GMP Professional (CPGP) Handbook has passed a major milestone. The draft manuscript was presented to ASQ Quality Press on January 12, 2014. This milestone marks nearly five years of work from several dedicated pharmaceutical quality professionals. Quality Press will have the manuscript professionally reviewed for content, after which preproduction work will begin. The preproduction process will include verification of the works cited, references, tables, and figures, and facilitation of the final editing process. We are confident (not statistically) that the handbook will be available at the World Conference on Quality and Improvement in early May 2014.

I would like to thank those who have contributed their knowledge and experience to this project as a chapter author and chapter editor. I would also like to recognize Martha Bennett for dedication and support—she will be missed.

Martha had more than 30 years of experience in the area of U.S. FDA law and regulations as an investigator, compliance officer, policy advisor to three commissioners, and consultant to companies worldwide regulated by the agency. She possessed strong analytical and communication skills, along with broad-based practical experience that she used to help clients develop sound regulatory and quality system programs. Martha provided litigation support as a consultant and expert witness. She was a Paul Harris Rotary Club Fellow and recipient of the Rotary Club Humanitarian Award. She was actively involved in ASQ, serving as the education chair for the Food, Drug, and Cosmetic Division. This first edition of the *Certified Pharmaceutical GMP Professional Handbook* is dedicated in memory of Martha Bennett. This handbook was planned and completed under her leadership.

Mark Durivge
CPGP Chair

Additionally, I wish to thank the Food, Drug, and Cosmetic Division leadership team for entrusting me with this project.

Going forward, I will be seeking volunteers for phase two of this project. Phase two will be the development of a CPGP refresher course based on the handbook. The plan is to develop a training curriculum that includes PowerPoint slides, handouts, and sample questions.

Ron Piervincenzi, Ph.D., Named CEO of USP

The board of trustees of the U.S. Pharmacopeial Convention (USP) announced that Ron Piervincenzi is the CEO of USP and chair of USP's standards-setting body, the Council of Experts. Piervincenzi assumed these responsibilities February 1, 2014.

"I am excited and honored to lead USP's mission to improve global health," said Piervincenzi. "This is an outstanding organization doing life-changing work around the world, and I look forward to focusing the collective energy, expertise, and knowledge of USP's global volunteers and staff on the challenges of the future."

"In Dr. Piervincenzi we have found an outstanding new leader for USP, which has seen unprecedented growth over the past several years," said USP board of trustees chair Thomas R. Temple. "I am excited about Dr. Piervincenzi's commitment to the next phase of USP's unique mission to develop and promote cutting-edge global standards for pharmaceuticals, food, and dietary supplements."

Piervincenzi was a partner and leader in McKinsey & Company's global pharmaceutical and medical products practice for 12 years where, among other responsibilities, he launched McKinsey's global drug safety, medical, and regulatory service line. Piervincenzi earned his MS and Ph.D. from Duke University in biomedical engineering with research focused on protein engineering.

Timothy R. Franson, president of USP added, "We have found an exceptional leader in Ron. His ability to motivate people, craft creative solutions to complex problems and the tremendous reputation and respect from his peers are the reasons why Ron was selected. We are delighted that he has accepted this challenge and are confident that USP is in great hands."

Ron Piervincenzki, Ph.D.
CEO of USP

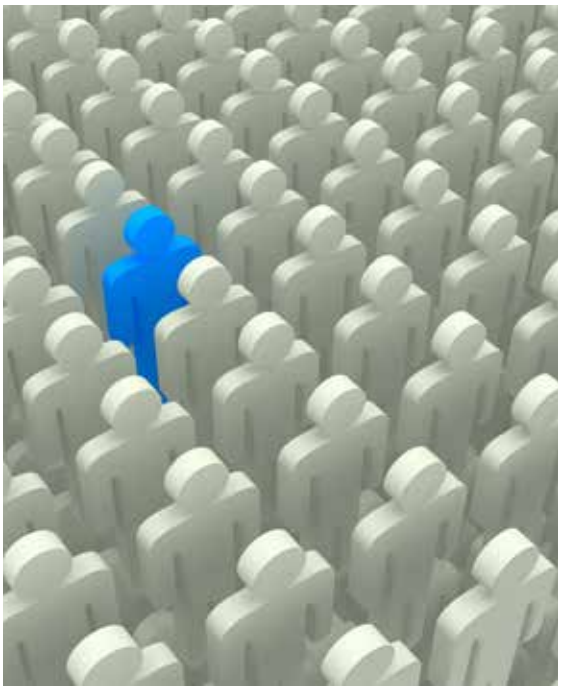
Outgoing CEO Roger L. Williams, MD, oversaw an unprecedented period of growth for USP. During Williams' tenure USP transformed from being an important standard-setting organization to a recognized leader in global health through the establishment of USP facilities in Africa, China, India, Brazil, and Europe. USP embarked on an ambitious effort to create new modernized standards in USP's compendia and through these efforts improve access to good-quality food and drugs. USP is also a key partner with USAID, working to combat the harmful influx of substandard and counterfeit medicines in developing countries around the world and improve lives through enhanced pharmaceutical standards.

"Dr. Williams has had a remarkable tenure. He has transformed this organization in an indelible way and been a driving force in improving public standards, and the organization is grateful for his lasting contributions," added Temple.

The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are used worldwide. For more information about USP visit http://www.usp.org.

WHAT EMPLOYERS WANT

Rosemarie Christopher, FD&C Division Chair 2012–2013



Know Your Worth

Do you feel like your organization does enough to identify, utilize, develop, and advance the high-potential talent right under its nose? The answer is probably no.

Internet chatter, discussions among HR professionals, career development magazines, and results from employer surveys all boil down to the same thing: Professionals must take career development into their own hands. Very few of us work for employers who "take care" of their employees. You must fend for yourself. That can be a little scary, and, believe it or not, empowering.

If you find yourself at a dead end, resist the urge to sulk and complain about your situation. Remember, the only person who can change your course is you. But before you make a move, spend some time reflecting in a positive way. You need to understand how valuable you are, what you value, and who will value you.

Know Your Organization

Learn about your current organization's history and structure, and determine if its modern-day embodiment fosters the development opportunities you are looking for. Some organizational cultures are heavily rooted in the past. Is your organization a relic from the Industrial Age with a hierarchical command and control structure that clashes with your out-of-the-box ideas? Does your organization's size create bureaucracy and a silo culture led by leaders who frown on your desire to acquire new skills and diversify your experience?

Younger organizations provide less structured environments and more opportunities for individual authority, autonomy, and contribution, which leads to higher levels of job satisfaction and fulfillment for some workers. There is a tradeoff, however. Start-ups are higher risk endeavors because there is less job security—in their first year, 25 percent of start-ups fail. By the fifth year, that failure rate is 55 percent. Further, because start-ups are entrepreneurial in nature, they demand employees who will be tirelessly committed and boast strong time and people management skills. Not everyone should ride the start-up wave.

Know Yourself

After 25 years in HR recruiting, I've developed insight into success. What is it about the five percent of technical and scientific candidates that differentiates them from the other 95 percent? First and foremost is a heightened sense of self and consciousness of purpose. There is no ambiguity. Every decision, discussion, or interaction comes from a place of enlightened self-interest.

To get in touch with your wants and needs, ask yourself these questions: Is there room to grow in your current role and organization? Are you fully using your strengths and experience most days? Have you made your mark as an individual contributor and are ready to take on a managerial role and be responsible for others? Does your job align with your preferred working style?

Today, the occupational landscape is diverse and limitless; careers exist today that didn't 10 years ago. For every command and control, brick and mortar workplace there's a virtual, self-directed team powered by W-2 contract employees and 1099 consultants. Everyone should know what they want and find—or create—a compatible role.

Know What Others Think

Your reputation is your best asset. Find colleagues and mentors who have opportunities to observe your behavior and performance, have an interest in your success, and are willing to speak openly and honestly. Once you've received this feedback, take time to reflect and evaluate what you've heard. The benefit of receiving feedback is a better understanding of strengths and weaknesses.

You don't need to be someone you're not—you just need to be the best version of yourself. Isolate what makes you unique as a professional and build your personal brand to help you market your value. You might learn you're missing some essential skills or credentials that can further enhance your brand. Growing a reputation that exudes professional excellence and personal continuous improvement is always a worthy investment.

Knowing yourself, your organization, and your reputation are the first steps toward aligning your current situation with your goals. Change can be hard. But by taking ownership you are really valuing who you are and what you want out of your career. To you, it might feel like organizations are stepping over dollars to pick up pennies. Show them what you're worth.

LinkedIn and ASQ

The next time you log in to your LinkedIn account, be sure to join the conversation with fellow *Global View* readers. Check out the Food, Drug, and Cosmetic Division on LinkedIn and also the Food Safety and Quality Network. Enjoy!

KEYS OF CAPA AND IMPROVEMENT

Akio Miura, ASQ Fellow, CQA, CQE, CRE, CMQ/OE, CSSBB, CBA, CHA, and CSQE

Editors Note:
This is part one of a two-part series that covers the keys of the corrective and preventive action (CAPA) system. Part two will be covered in subsequent newsletters.

Safety, sanitation and health, and a clean working environment are the most important prerequisites for the industries related to food, drug, and medical devices. These are among the highly regulated industries and must follow and comply with local federal regulation. This is mandatory. Prevention of any undesirable situation in these issues is indispensable. If any such situation or problem is identified, correction and corrective action must be performed immediately.

I have heard that many companies and quality-related people, including registrars and auditors of ISO standards, are quite often confused in interpretation of the terms corrective action (CA), preventive action (PA), correction, and improvement, because these terms are different from each other although they look similar. Another reason for this confusion is that there is no definition of "improvement" in ISO 9000 series standards.

Most confusing is the difference between correction and improvement. Improvement is some change to make a good thing better, i.e., betterment. However, many recent lean Kaizen practitioners view/understand it as to be "changing or tampering something in the process for no good reason" as "improvement." According to a report from Japanese research institute Nihon Soken published around 1990, the result of 99 percent of Kaizen cases in Japan turned out to be "only less bad" or even "from bad to worse." Are you satisfied with "less bad" or will you allow it to be called betterment? I do not recommend the attempt of making such changes.

As to these terms, various questions have been raised in ASQ Discussion Forums and my own courses in the past 15 years. I would like to first explain the differences between these terms by summarizing all of my responses in the section to follow.

Corrective Action and Correction

CA and correction are the action for resolution of the problem.

Problems here may be:

- Nonconformity to applicable regulations and standards.
- Other undesirable situations such as: defects, deficiencies, error, failure, and trouble in any product, activity, process, and/or management system.

CA is the action to prevent the recurrence of the problem that actually occurred. It relates more to the system, process, or other factors than the individual item.

Correction is to fix or correct wrong things to make them right. It is for each individual item. In management practice, correction is a type of disposition. Types of disposition are:

- Type 1: Remedial action – correction of product
- Type 2: Correction of situation

The correction is directly applied to the defective or deficient part of the individual product to fix it by repair, rework, or reprocessing. For correction, there are two cases. One is for the individual product (Type 1). Another is for the result of activity (Type 2).

While correction and other types of disposition are applied only for each individual product, CA is the action to eliminate the root cause to preclude the recurrence of the problem after the quick fix of the problem. CA involves the change in things other than the individual product or problem; mostly, the change in some control factors in the management system, such as procedures, product design, process, equipment, and management system itself, as the permanent measures. Correction is like firefighting, while CA is like fire prevention.

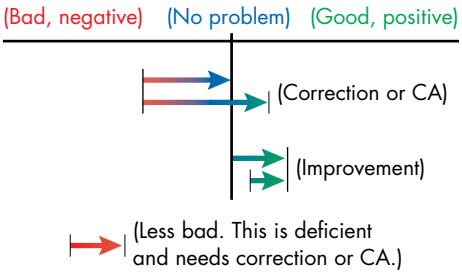
Corrective Action Versus Preventive Action

PA is the action to prevent the occurrence of the potential problem before it occurs by eliminating its underlying cause. PA aims to keep a problem from ever happening. PA occurs before a problem, while CA occurs after a problem. CA looks back in time, while PA looks forward in time. We call CA and PA "CAPA" collectively.

Corrective Action Versus Improvement

Figure 1 shows the difference between these terms from a practical view point.

Figure 1. Corrective Action Versus Improvement



CA precludes the recurrence of the problem that has actually occurred by making bad stuff good when any problem is identified, while improvement is limited to those changes that make it better when there is no problem. CA is "bad to good" (or "at least bad to not bad"), while in my own words, improvement is "good (or at least not bad) to better," by making a strong point stronger, like "reinforcement."

I have noticed that many quality-related personnel assume CA is for the audit findings for the FDA approval or the ISO registration. We have to be aware that CA is for all undesirable situations for the company such as customer complaints and internal failures, which may be more serious than those for external audit findings. As the clauses in the FDA regulations and ISO standards are the least minimum requirements for the company management, the company has to be entirely in compliance with the regulation from the beginning. The requirements are not stringent but very reasonable. If they get registration audit findings, it means they are violating regulations. So such companies that cannot comply with the regulations shall be disapproved or disqualified.

Preventive Action Versus Improvement

PA precludes the occurrence of the problem when there is any fear of a potential problem. Improvement should strengthen the good points and occur when there is no potential problem. Improvement is limited to those changes

that make it better when there is no actual or potential problem.

There are cases where the upper limit is 100 percent or perfect. In such cases, it is an improvement if a good thing is made closer to that limit. As you know, some people urge "continual improvement" effort by misinterpretation of requirements for ISO certification. Is the improvement necessary for the product or process that is 100 percent OK or with zero defect? Can there be such a thing as 105 percent perfect or minus one piece of defect?

Many companies and people looking at only FDA approval and ISO registration—including personnel in ISO headquarters and registrars—apply CA to the same findings or problems identified at the ISO assessment audits continual improvement with the PDCA cycle. If you have to repeat the CA for one problem, it means that such CA was altogether ineffective and deficient. It is "putting patches to holes." Also, tampering with the good system would destroy the system. By this reason, the FDA does not encourage continual improvement required in ISO 9001.

If the company has established a good management system with appropriate processes and procedures for doing right things right, there will be only a few situations that need CAPA, and that will help the company avoid repeating the same CA and mistakenly calling it continual improvement. Therefore, implementing a good system and procedures may be the best way for the company to prevent problems. The FDA GMP regulations are not as stringent as many people think. They are very reasonable and good practices for company management.

Part 2 in the next issue of this newsletter will discuss the keys points for CAPA management.

About the Author:
Akio Miura has been a quality management consultant in Tokyo, Japan since the 1980s, and has helped more than 100 companies in Japan and some in the United States establish management systems and get certified to ISO 9000 series, cGMP, and other major quality management standards. He is an RAB-IATCA-approved ISO Lead Auditor Training Course instructor. He has promoted ASQ exams in Japan and Asian countries since 1995, and serves as a country counselor of ASQ's Quality Audit Division and the Food, Drug, and Cosmetic Division. Miura has volunteered as an active contributor to the ASQ Discussion Forum since 2002.

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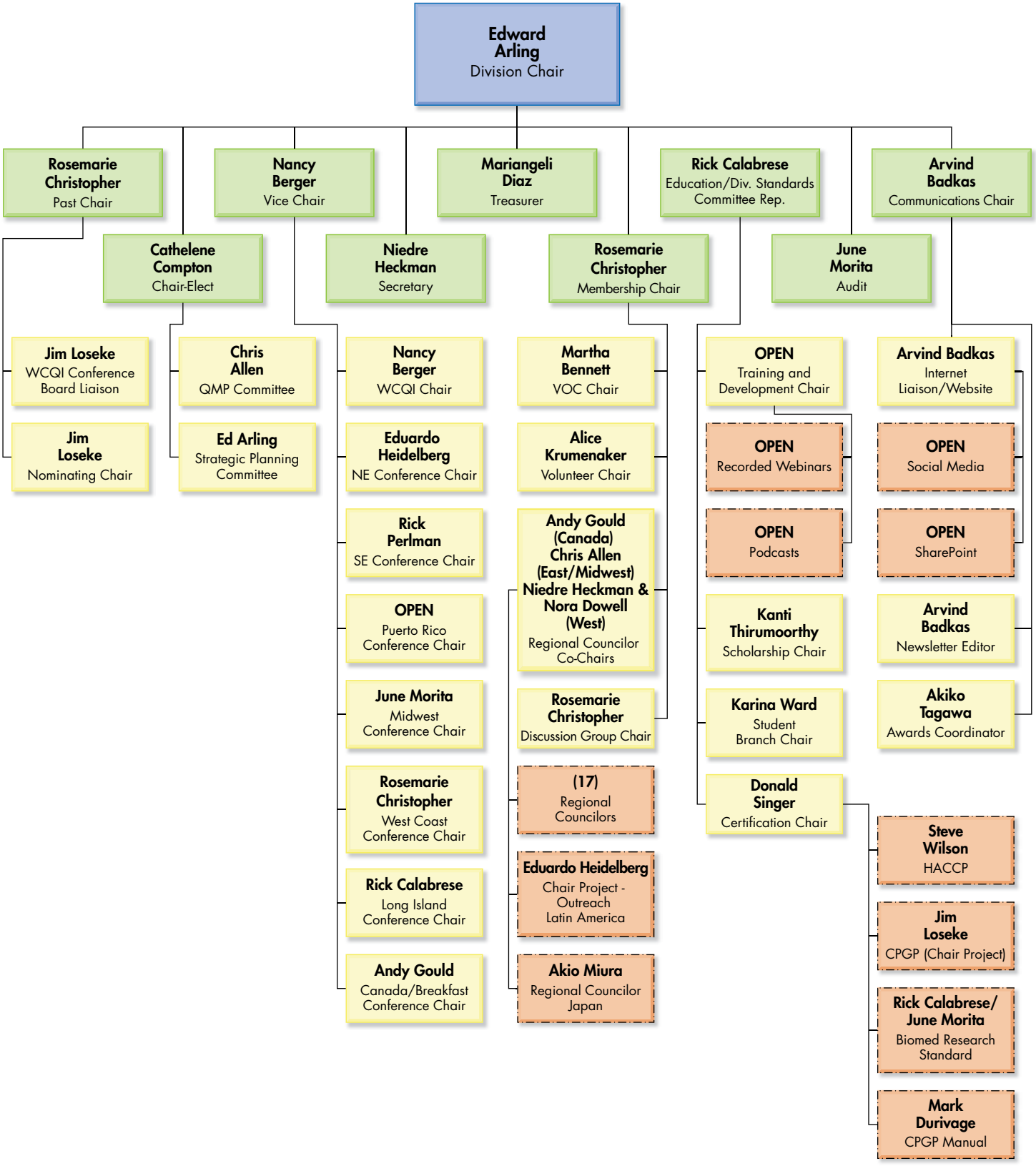
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