



ASQ

AMERICAN SOCIETY FOR QUALITY™



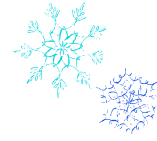
Chicago

Newsletter of Section 1201
January 2005



Vol. 4
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General Meeting – Main Session Quality Systems within the Pharmaceutical Industry



Have you ever wondered what it takes to get a new drug to market? Are you curious about the Food and Drug Administration? How and why was the FDA created? What kinds of regulations exist? If the drug is FDA approved, does it mean it's safe? Why are some drugs taken off the market? How are Quality Systems a part of drug development? Would you want to work in the pharmaceutical industry?

If the answer is yes to one or more of these questions, this talk will be of interest to you. The topics to be covered include:

- FDA's history
- FDA's mission
- Primary functions of the FDA
- Key laws enacted
- How Regulations are developed
- Drug development process
- Discovery
- Non-clinical work
- Investigational New Drug Application
- Clinical studies
- New Drug Application
- Post-marketing Activities

Speaker's Bio

Catherine Johnson, RAC (Regulatory Affairs Certification), has a BS in the Biological Sciences, and she has worked in the pharmaceutical/medical industry for a long

time. She refuses to say how long because it would give away her age, but I did hear her mention a field trip she once took with Darwin. Catherine has worked both in the quality and regulatory affairs areas in such diverse companies as Alberto Culver, Blistex Corporation, Medical Specialists in Packaging Inc., Baxter Healthcare and TAP Pharmaceuticals. Most recently she has been working as a Quality Performance Manager and has spent her time establishing and maintaining a quality system at TAP Pharmaceuticals. On a personal note, Catherine writes screenplays and once won a Best Lips contest sponsored by Blistex. •

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Register for General Dinner Meetings at www.asqchicago.org



Coming Events



ASQ Certification Exam Dates

2005

Certifications	Application Deadline	Exam Date
CQT, CRE, CMI, CHA, CQM, CSSBB	Jan. 7	Mar. 5
CQE, CQA, CSQE, CQIA, CCT	Apr. 1	Jun. 4
CQT, CRE, CMI, CHA, CQM, CSSBB	Aug. 19	Oct. 22
CQE, CQA, CSQE, CQIA, CCT	Oct. 7	Dec. 3
Questions? Call Hari Soni at (847) 579-3231		

Recertification 411

Do you need to recertify? Are you due anytime soon? Has your deadline passed and you're thinking, "Uh-oh"? Are you way passed due? Way, way passed due? Perhaps short some CEU's or RU's? Not working, unemployed and think you don't have the employment credits?

Don't let this get you down and don't give up on those certifications. You worked hard to get them.

FEAR NOT! Contact the Recert Guy, Ed McCarthy, Recert Chair at 708-457-4066 or e-mail emccarthy@methode.com. He will get you through the recertification process. No Section 1201 member will lose a certification if they don't want to – and you heard it here first! •



November's General Meeting Review

By Lela S. Perteet, Chair-Programs

Congratulations to all Recognition and Service Awards recipients. A special Thank You to family members and friends who came to show support for the recipients. We appreciate your continued support throughout the program year. 110 guests attended the November dinner meeting, held at the Wellington of Arlington Heights. Overall Satisfaction score was 100%.

Paul E. Borawski, Executive Director of ASQ, presented the main session. Paul shared the strategy and trends for the quality profession. Highlights included seven key forces: 1. Quality must deliver bottom line results; 2. Management systems absorbing quality functions; 3. Quality will be everyone's job; 4. Economic case for broad application of quality required; 5. Global market and workforce; 6. Declining trust and confidence everywhere; 7. Rising customer expectations. Paul presented an excellent business case demonstrating that ASQ is an organization on the move. His presentation was very informative and can be viewed by visiting www.asqchicago.org.

Raffle Prize Winners

Congratulations to the 4 raffle prize winners who each received a \$25 gift certificate.



Thanks to the Volunteers

Richard Heller, Dan Brown, Dan Montgomery, Sam Makwana, Tricia Farley, Larry Stawicki, Jim Walker, and Lela Perteet. •



General Meeting – Advance Session Prioritization with Executive Buy-in



Invide your executives and co-workers. This presentation will help quality professionals understand the dynamics, tools and benefits that can be bench marked to maintain executive support for the successful completion of projects in a continuous improvement organization.

Overview

According to the Project Management Institute, the main reasons projects fail:

- 43% due to the lack of executive support
- 38% due to scope creep
- 11% due to project team politics
- 8% due to lack of resources

(Source: *PM Network*, May 2004)

Learn how Rush University Medical Center has developed and implemented an ongoing streamlined process to evaluate and prioritize initiatives in order to optimize business benefits. Key components of the process include:

- Business leaders who understand their business choose project priorities
- Project selection based on consistent benefit criteria rather than politics or emotions
- Determination of a viable project mix that meets the goals of the organization
- Continuous analysis of the portfolio performance

and ways to improve it

- Continuous evaluation of new opportunities in relation to the current portfolio.

Speaker's Bio

Susan Nauseda is the Director of the Program Management Office (PMO) for Information Services at Rush University Medical Center. At Rush she has implemented an ongoing process for project prioritization and portfolio management by key business executives. Susan was a member of the Project Management Office at Cambridge Technology Partners (an e-business implementer) where she implemented the project management methodology for the organization. She also worked at CNA, GE Medical Systems and the University of Chicago Hospitals in various PMO roles. Susan has earned an MBA with a concentration in Systems from DePaul University and is also a certified Project Management Professional (PMP). •



Do You DARE to be a Team?

Submitted by Tricia Farley

Recently I read an article by Baylor professor Phil VanAuken. I was very surprised by what he said about rewards. It was so basic and yet so profound. I have read and studied team building, but his words really made me look deeper into the concept. Can I really buy his assumption that the four basic human needs can only be met in a group? Can I really agree that all human need can be summed up in four key terms? Can it really be so simple? Here is an excerpt and you be the judge. If you would like to see the article in its entirety go to the ASQ Chicago Section website at www.asqchicago.org. A link to other works by Mr. Van Auken can be found there as well.

Do You DARE to be a Team?

by Phil Van Auken, *Supervision* magazine, 1/97

The Teamwork era is here in full force. Has it arrived in your organization? Companies of every size and pedigree are striving today to team up employees for heightened productivity, better customer relations and simplified structure ("downsizing"). In just a short time, teamwork has become the rallying cry for progressive organizations and their training initiatives.

(Continued on page 5 - DARE)



Lean Manufacturing – part 2

©By George Alukal

Brief History of Lean

Most of the Lean concepts are not new. Many of them were being practiced at Ford during the 1920s, or are familiar to most industrial engineers.

A few years after the second World War, Eiji Toyoda of Japan's Toyota Motor Company visited the American car manufacturers to learn from them, and to transplant U.S. automobile production practices to the Toyota plants. With the eventual assistance of Toyota's Taiichi Ohno and Shigeo Shingo, he introduced and continuously refined a system of manufacturing whose goal was the reduction or elimination of non-value-added tasks (for which the customer was not willing to pay). The concepts and techniques that go into this system are now known as Toyota Production System or T.P.S., and were recently re-introduced and popularized in America under the umbrella of "Lean Manufacturing".

Lean concepts are applicable beyond just the shop floor. Companies have realized great benefit by implementing Lean techniques in the office functions of manufacturing firms, as well as in purely service firms such as banks, hospitals, restaurants, etc. Lean manufacturing in this context is known as "Lean Enterprise".

American Society for Quality (ASQ) has seen a steady increase in the demand among its members about Lean, as evidenced by the attendance and interest in Lean presentations at the recent Annual Quality Conferences, the new two-day seminars on Lean being offered by ASQ as part of their career-based Training Programs, and the recent formation of a new Forum titled "Advanced Manufacturing Forum" (AMF) for ASQ members to participate in Lean-based activities. Similar interest is seen by the Society of Manufacturing Engineers, Association for Manufacturing Excellence, APICS, etc. as well.

The "Wastes (or "muda" in Japanese) of Lean Waste of resources has direct impact on our costs, quality and delivery. Conversely the elimination of wastes results in higher customer satisfaction, profitability, throughput and efficiency. Excess inventory, unnecessary movement, untapped human potential, unplanned downtime and sub-optimal changeover time are

all symptoms of waste.

Cutting out the eight wastes of Lean (described in detail in the November 2004 issue of the ASQ Chicago Section newsletter) is the major objective of Lean implementation. The continuous reduction and/or elimination of them results in surprisingly high reductions in costs and cycle times. If we were to do a root cause analysis of each of the eight wastes, we can come up with the appropriate Lean tool to tackle the causes identified. If, for instance, long lead times and missed delivery dates are major bottlenecks, identifying the underlying reasons might lead us to focus in on set-up times, machine downtime, absenteeism, missed supplier shipments, quality problems, overproduction resulting in excess inventory, etc.

Waste

Eliminate waste by identifying and purging all non-value-added activities:

- Waste is any activity that does not add value to the final product for the customer.
- Value-adding activity is an activity that transforms or shapes raw material or information to meet customer requirements. Approximately 5% of total work/time
- Non-value-adding activity is an activity that takes time, resources or space, but does not add to the value of the product itself. Approximately 70%
- Non-value-adding but necessary – e.g., accounting, governmental regulations; etc. Approximately 25%

Let us look at one example in detail: the primary reason for overproduction and carrying excess inventory might be due to long process changeover times, in which case the correct tool (or "Lean building block") to use will most likely be SMED (Single Minute Exchange of Dies) or Quick Changeover Techniques.

Changeover time is defined as "the time between the last good piece off the current run and the first good piece off the next run". The traditional changeover assumption is that long runs are necessary to offset the cost of lengthy change-

overs. This is not valid if the changeover time can be reduced as far as possible (under 10 minutes if the SMED technique is applicable), and standardized at that level so that we are confident that a good piece from the next run can be made in a certain time period. The changeover improvement process typically includes the following steps:

- Identify and form the changeover improvement team (operators, manufacturing/quality engineers, set-up specialists, material handlers, tool/jig/fixture makers, maintenance technicians, supervisors/team leaders, etc.).
- Document the current changeover (video-tape where possible).

(Continued on page 5 - Lean)

(Lean . . . continued)

- Through brainstorming, analyze the changeover and identify ways to reduce, eliminate, consolidate or mistake-proof steps and convert from internal to external time/tasks. “Internal” time is when the machine is stopped, whereas “external” time is when the machine is running producing the previous part.
- Implement improvements and monitor results.
- Streamline all aspects of set-up operations.

Now standardize the improved changeover.

Besides attacking overproduction/inventory wastes, quick changeover can result in the reduction of lead time, defective product and space requirements while improving productivity, flexibility, and smaller batches with more variety (mass customization).

Many of the wastes could be associated with variations in processes; statistical tools, including the Six Sigma DMAIC (Define-Measure-Analyze-Improve-Control) methodology might be appropriate to attack such wastes. Lean and Six Sigma, thus, are not mutually exclusive—rather they are complimentary. Some firms use the appropriate combination of Lean, Six Sigma, Theory of Constraints and elements of TQM in their constant strive for continuous improvement and competitive advantage.

The following lists some of the causes of variation and waste:

- Poor layout
- Long set up time
- Poor workplace organization
- Poor equipment maintenance
- Inadequate training
- Use of improper methods
- Statistically incapable processes
- Not following procedures
- Instructions/information not clear
- Poor planning
- Supplier quality problems
- Inaccurate gauges
- Poor work environment (e.g., light, heat, humidity, cleanliness, clutter, etc.)

Those interested in ASQ’s Advanced Manufacturing Forum and the Lean Manufacturing Users Group can contact George Alukal at (773) 551-0836, (312) 542-0445 or e-mail at galukal@cmcusa.org. The first meeting is scheduled at the Tooling & Manufacturing Assoc. 1177 South Dee Road, Park Ridge, on Wednesday, January 12, 2005 from 8-10:00 a.m. •

(DARE—Continued from page 3)

Taking the DARE

Teamwork has a special alchemy consisting of four ingredients:

- Dependency**
- Accountability**
- Reward**
- Empowerment**

Rewards

Everyone loves to be on a winning team – it can be an exhilarating experience. However, we live in a culture where people like to take credit for success more than give credit. That’s tough on teamwork. Teams need members who are content to stand in the team’s shadow rather than in the spotlight.

The rewards of team membership often go unrecognized in our individualistic culture, but those who are willing to sublimate themselves in the larger team entity experience rich returns--the kind that make it worth coming to work every day.

Only in a team environment are our four deepest human needs met, which can be expressed as the four "I ams" of teamwork: I am needed, I am unique, I am productive and I am appreciated. Our multifaceted contributions to the team help us define who we are, why we're worthwhile and how our work is meaningful. These needs lie at the very core of what motivates us and they bond us to the organization.

This explains the powerful pull of sports teams, social clubs and even street gangs. Their members gain a sense of identity and acceptance in return for their loyalty to the team.

People will work hard for their team, even to the point of personal sacrifice. Thus, the rewards of teamwork extend to the whole organization—if management dares to go beyond the traditional rewards of money, perks and status which often promote maverick individualism. Leaders must strive to deliver the psychological rewards of teamwork along with fair pay and financial benefits. This requires an empowering organization culture. •



The New Registration and Check-in Process for Dinner Meetings

Pay Pal and the Check-in Process

Special thanks to Boyce Grier, Ray Wick, Sam Makwana, Bonnie Jo Trent and Lela Perteet for supporting this initiative. Secure On-line registration was tested in October and November. Thank you for providing feedback to make this continuous improvement a success. Cumulative, 98% of you have expressed complete satisfaction with the check-in process, 93% are satisfied with on-line registration. While we are pleased with the scores, we solicit your input as work continues to streamline the on-line registra-

tion process. We believe that these changes have provided value-added benefits by providing our members with more payment options, secure on-line payment options, immediate on-line notification and receipt (final receipt is provided at dinner meeting), an extended registration and cancellation deadline, improved cycle time for processing registrations and a significant reduction in time required for the check-in process at dinner meetings. •

Old Method	New Method – Pay Pal
Accepted only AMEX, Visa, Master Card	Accept AMEX, Visa, Master Card, Discover, and E-Check
Long lines at check-in	Check-in time less than 2 minutes
Not secure, manual process	Secure payment method, on-line
Delayed notification	Immediate on-line notification and receipt
Registration close at 5:00 p.m. Friday before dinner meeting	Registration close at 5:00 p.m. Monday before dinner meeting
Registration cost of \$4.00 per member per dinner meeting	Registration cost of \$1.03 per member per dinner meeting
<i>Thank you for managing change</i>	



Networking Corner

Tips from the *Adams Businesses You Can Start Almanac*

The following are some proven tips for successful networking:

- **Develop as many contacts as you can.** Set a challenging goal, add one new person each day, and you'll have met at least twenty new people per month.
- **Tell people the one thing you feel you do best** in your 30 second summary. Don't give them a rundown of all that you can do. It confuses, and even annoys, some people when the conversation seems one-sided; be concise about what you do so that the other person may reciprocate.
- **Become a host and leader, not a wallflower.** Show initiative; introduce yourself. Do not throw your card at anybody until after you've established a verbal introduction.
- **Cultivate you contacts.** Do not try to use the situation to get immediate business; instead, ask to meet privately later on. Nobody likes to feel pressure in social situations.
- **Extend your own expertise first whenever possible.** Be available to those who call on you for help when they need it.
- **Keep in touch.** Mail or fax articles that might be of interest to your contacts-it shows you were listening when you met them, and that you remembered what they said.

Bring your business cards and practice your 30 seconds summary •

Happy Holidays and have a Great New Year



From the ASQ Chicago Board and Volunteers

Chicago Section General Meeting – January 12, 2005	
<u>Location</u>	<u>Program Schedule</u>
La Mirage	5:30–6:00 p.m. Check-in / Networking
3223 Algonquin Road	6:00–7:00 p.m. Advance Session
Rolling Meadows, IL 60008	7:00–8:00 p.m. Dinner
(847) 222-1222	8:00–9:00 p.m. Main Session

Directions: From I-90 (Northwest Tollway) turn off ramp towards Arlington Heights, Bear RIGHT (North) onto S. Arlington Heights Road for 0.1 mile. Turn LEFT (West) onto SR-62 (W. Algonquin Road) for 2.2 miles. Arrive at 3223 Algonquin Road, La Mirage.

How to Register

- Register on-line at www.asqchicago.org/onlinereg.htm and complete the required information.
- Because walk-ins are limited and subject to availability, please register prior to the meeting.
- Fax and telephone registrations are currently being discontinued.
- Registration and payment on-line is *secure*.
- *The first 25 who register on-line will be entered into a \$25 raffle.*

Cost

- **Registration** - payment required at time of registration: members \$25, nonmembers \$30
- **Walk-ins** - subject to availability, cash or check only: members \$30, nonmembers \$35
- **Program only** - attendance without dinner, no charge, registration is required
- **Unemployed members** - special provisions are available, registration is required

Notes

- No credit cards accepted on night of meeting.
- No refunds will be made for cancellation after 5:00 p.m., Monday, January 10, or for a no-show at the meeting.
- Accepted credit cards: Personal - American Express, Discover, Master Card, Visa
Corporate - Master Card, Visa
- Questions? Call Lela Perteeet at (773) 640-7169. •

ASQ Newsletter Information

Subscription Information and Address Changes

Subscription to the newsletter is provided as long as your membership with ASQ is current, and you are registered with the Chicago Section. Your address and other contact information are maintained by ASQ headquarters and can

be changed on the ASQ website: www.asq.org. ASQ Members sign-in and change address.

Questions regarding the Newsletter? Contact Norm Peplow at (630) 968-0267 or www.npeplow23@aol.com. •





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The Society of Professionals Dedicated to the Advancement of Quality

Chicago Section General Meetings for 2004-2005

	Date	Location	<u>Program Topics</u>
			Advance / Main Sessions
Questions? Contact Lela Perteet at (773) 640-7169	—	Maggiano's, Oak Brook	Presentation of the Chicago ASQ Board, Services & Goals / Using Customer Input to Drive Organizational Improvement
	—	Manzo's, Des Plaines	How to Search for a Job / Save American Manufacturing
	—	Wellington of Arlington, Arlington Heights	Recognition / The Future of Quality
Register at our website www.asqchicago.org	1/12/05	La Mirage, Rolling Meadows	Prioritization with Executive Buy-In / Quality Standards
	2/9/05	Maggiano's, Oak Brook	Performance Dash Board – The Continual Improvement Process / Leading Change
	3/9/05	Oak Meadows, Addison	Team Effectiveness
	4/13/05	Ripples of Darien	Building an Effective Network / Risk for Quality Improvement
	6/8/05	TBA	Joe Lisy Award Dinner

General Meetings are held on the 2nd Wednesday of the month.